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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
Arnold Schwarzenegger, GOVERNOR

Enforcement Committee Report

William Powers, Public Member, Chair
Stan Goldenberg, RP.h.
David Fong, Pharm.D.

Report of September 29, 2004

FOR ACTION

RECOMMENDATION 1

That the Board of Pharmacy support a statutory change to Business and Professions Code sec. 4360 - 4373 to update the law regarding the Pharmacist Recovery Program.

Discussion
The purpose of the proposed changes is to update the statutory provisions related to the Pharmacists Recovery Program (program). Most of the proposed changes are minor, technical revisions to more closely conform the statute to the current operation of the program, however there are some substantive changes.

The most substantive change effects section 4362. This section specifies who is eligible to enter the program and the terms of entry into the program. First, a licensee can be referred to the program instead of or in addition to disciplinary action. Second, a licensee can enter the program voluntarily. This largely reflects current operation of the program.

The substantial change made is that licensees that enter the program voluntarily will not have their identities withheld from the board. Current law indicates that such "self-referrals" are confidential and the board is generally not informed of their identities. This "confidentiality" can be voided if the program administrator believes the licensee may present a threat to the public. However, participants sign disclosure agreement upon entering the program that permits the program to release their identity to the board. This statutory change would conform to existing practice by the program.

The draft proposes to prohibit the board from taking enforcement action against the self referred licensee based on their entry into the program or any information obtained from the licensee while participating in the program. This change more closely mirrors the diversion programs operated by other boards in the department. The proposal does allow the board to take an

enforcement action against a licensee in the program if the board independently obtains information supporting such an action.

Another substantial change is to section 4368, which removes the mandate that the board enter into a contract with a professional association to promote the program and coordinate outreach to encourage voluntary participation. The board has not entered into such a contract with a professional association for over five years. Given the current fiscal constraints on the board, it is unlikely that such a contract would be reestablished in the foreseeable future and removing the statutory mandate would seem appropriate. The board can use other means to educate licensees about the availability of the program. The board could always enter into such a contract, if it desired, without the statutory mandate.

It was asked if the board had considered including pharmacy technicians in the program. It was noted that the intent is to rehabilitate pharmacists so that they may return safely to the practice of pharmacy. As a health professional, the pharmacist has much more invested in their education and training and thus more incentive to seek treatment. The program also encourages the pharmacist's participation and rehabilitation while providing the oversight necessary to ensure patient safety without undue punishment to the impaired pharmacist. **(Attachment A)**

RECOMMENDATION 2

That the Board of Pharmacy support a statutory change to Business and Professions Code sec. 4038, 4114, 4115, 4115.5 and 4202 related to the pharmacy technician program.

Discussion
The proposed changes to the pharmacy technician program are primarily technical and designed to make the statutes more clear. The most significant change is standardizing the terminology relating to the supervision of ancillary personnel. The different code sections used slight variations of language requiring the supervision of ancillary personnel. This draft adopts the most common verbiage of "direct supervision and control" of the pharmacist and applies this same supervision to interns.

The other changes are mostly technical clean up to eliminate duplicative and unnecessary language. However, one substantive change to 4115 is made to eliminate the exemption that permits unlicensed personnel to act as a pharmacy technician during their first year of employment at the Department of Corrections, California Youth Authority, Department of Mental Health, Department of Developmental Services or the Department of Veterans Affairs. This provision was added to allow personnel to work in those facilities until they could accumulate enough hours to qualify for licensure as a pharmacy technician. However, experience is no longer a means of qualifying for licensure as a pharmacy technician and this provision is no longer appropriate.

Comments were made that provided general support with the proposed changes with an opportunity for the board to consider some possible enhancements. It was reiterated that the intent of this legislative proposal was not to change the ratio or the basic authority of pharmacy

technicians. As legislation is introduced, the opportunity to address these issues is always available. **(Attachment B)**

RECOMMENDATION 3

That the Board of Pharmacy support a statutory change to Business and Professions Code sec. 4315 related to the Letter of Admonishment.

Discussion
Section 4315, which authorizes the executive officer of the board to issue a letter of admonishment for a violation of the Pharmacy Law, was added last year to provide the board with a broader range of enforcement options. One requirement in the new section is that the licensee receiving the Letter of Admonishment must keep a copy of that letter in the pharmacy for three years. This requirement is problematic for licensees that do not work regularly in the same pharmacy or do not work in a pharmacy at all (exemptee, wholesaler, etc.). **(Attachment C)**

RECOMMENDATION 4

That the Board of Pharmacy support a proposed regulation change to implement SB 1913 related to the use of technologies to record the identification of a reviewing pharmacist.

Discussion
Senate Bill 1913 amended Section 4115 to permit the board to allow the use of electronic technologies to satisfy the requirement that a pharmacist sign off on prescriptions filled by pharmacy technicians. The proposed regulation text would allow the use of electronic methods of identifying the reviewing pharmacist. This section would also be an alternative means of documenting the pharmacist's review as required by CCR, title 16, sec. 1717(b)(1) and 1717(g). **(Attachment D)**

RECOMMENDATION 5

That the Board of Pharmacy consider a proposed regulation change to CCR, title 16, sec. 1715, an update of the pharmacy self-assessment forms.

Discussion
This regulation requires that a pharmacist-in-charge (PIC) perform a self-assessment by July 1, of every odd year. It is the board's intent to update the self-assessment forms with the many law changes in advance of the July 1, 2005 mandate. To do this, the board needs to notice and act on the regulation change at the January board meeting. The revisions to the self-assessment forms had not been completed for the Enforcement Committee meeting. **(Attachment E – Community Pharmacy Self-Assessment and Attachment F- Hospital Pharmacy Self-Assessment)**

RECOMMENDATION 6

That the Board of Pharmacy consider the request from Longs Drug Stores for a waiver of 1717(e) to install a 24-hour kiosk for patients to drop off their prescriptions.

Discussion
Longs Drug Stores is requesting a waiver of CCR, title 16, sec. 1717(e) to install convenient, secure and private, 24-hour prescription drop kiosks. The plan is to install the kiosk adjacent to or in the parking lot at various Longs Drug Stores in California, for patients to use as an easy means to drop off their prescriptions for the pharmacy to fill. The kiosk would be similar to a mailbox or drop off container used by video stores. **(Attachment G)**

An E-mail from Lowell McNicol that had an article on dental hygienists was also provided in the attachment. He asked that it be included because it has bearing on the discussion regarding "kiosks" and the next agenda item regarding "automated dispensing devices."

Counsel has advised that a waiver of the prohibition in 16 CCR § 1717(e) is required, under the authority of that section, to permit Longs to move forward with this proposal.

The Enforcement Committee advanced to the Board of Pharmacy this request from Longs Drug Stores for waiver of 1717(e) to use a 24-hour prescription drop kiosk; however, the committee did not make a recommendation regarding the request. Prior to the presentation by Longs Drug Stores, board member David Fong recused himself from the discussion.

RECOMMENDATION 7

That the Board of Pharmacy consider the request from Longs Drug Stores for a waiver of 1717(e) to install and use a self-service dispensing unit for refill prescriptions.

Discussion
Longs Drug Stores is requesting a waiver of 1717(e) to install and utilize a self-service dispensing unit, such as the Asters ScriptCenter, at various Long Drug Stores in California.

The Asters ScriptCenter is an automated, self-contained instrument that allows patients to access their filled prescriptions. The intent is to install the units in close proximity to the pharmacy area. To improve patient convenience and therapeutic compliance, a patient may access the units during pharmacy hours or during those times when the main store is open, but the pharmacy is closed.

At the request of the patient and through the use of a secure method designed to guard against inappropriate access, a patient may retrieve his/her filled prescription from the unit at their convenience. New prescriptions, or those prescriptions requiring consultation, would not be available through these units.

Prescriptions would be filled by a pharmacist and placed into the units either by a pharmacist or pharmacy personnel, under the supervision of a pharmacist. As medications are placed into the units, security measures are used to ensure accurate dispensing. **(Attachment H)**

Counsel has advised that a waiver of the prohibition in 16 CCR § 1717(e) is required, under the authority of that section, to permit Longs and/or Asteres to move forward with this proposal.

The Enforcement Committee advanced to the Board of Pharmacy this request from Longs Drug Stores for waiver of 1717(e) to use a self-service dispensing unit; however, the committee did not make a recommendation regarding the request. Prior to the discussing the request from Longs Drug Stores, board member David Fong recused himself.

RECOMMENDATION 8

That the Board of Pharmacy consider a proposed regulation change to add CCR, title 16, sec. 1713 related to the delivery of prescriptions and prescription medications.

Discussion
Based on the request from Longs Drug Stores to permit the use of a secure drop box for receiving prescription orders from patients and to use a self-serving secure device for dispensing filled prescriptions, staff drafted a regulation change that would permit both these activities should the board grant the waivers.

The prescription drop boxes would allow patients to drop off prescriptions in a secure container that is at the same address of the pharmacy or adjoining the licensed premises. The secure devices would be for dispensing refill prescriptions not subject to the consultation requirement and originally was limited to when the pharmacy was closed. However, as counsel advised, the proposed regulation would need to be modified to allow the use of these devices when the pharmacy is open as well as closed. It was modified after the Enforcement Committee meeting by removing the "closed pharmacy" restriction. The proposed draft relocates existing provision 1717(e) into a new section and provides the authorization for both the drop boxes and self-service dispensing devices. **(Attachment I)**

Concern was expressed that the Board of Pharmacy should not act on this proposed regulation or the waiver request to use the self-service dispensing device until the board has a philosophical discussion regarding pharmacist consultation on refill prescriptions. Currently, the law doesn't require pharmacist consultation on refill prescriptions (only in the pharmacist's professional judgment or upon a patient's request); however, it was argued that the use of these self-service dispensing devices would remove the pharmacist completely away from the process. It was noted that pharmacy law doesn't require the pharmacist to physically provide the patient with the refill medication; a cashier does this.

The Enforcement Committee moved this proposed regulation to the Board of Pharmacy for its consideration. The committee did not provide a recommendation.

NO ACTION

Importation of Prescription Drugs

Background information is included on the activities related to this issue since the last board meeting. It was noted that the Governor had not yet acted on the various legislative proposals that would assist Californians in obtaining prescription drugs from Canada. One bill, AB 1957 (Frommer) would require the Department of Health Services (DHS) to establish a program that would provide information to consumers and health care providers about options for obtaining prescription drugs at affordable prices and would require DHS to establish a web site before July 1, 2005 to various drug benefit programs including Canadian pharmacies that meet certain standards. One of the standards is that the Canadian pharmacy meets the requirements of a nonresident pharmacy.

Another bill, SB 1149(Ortiz) would require the Board of Pharmacy to establish an interactive Internet Web site to identify licensed Canadian pharmacies that meet specified standard criteria for the safe acquisition, shipment, handling, and dispensing of prescription drugs to persons in California. One of the standards is that the Canadian pharmacy meets the requirements for licensure by the board. The board opposed this bill at its last meeting.

The committee was also given a copy a letter from Governor Schwarzenegger to Secretary Tommy Thompson dated August 20, 2004, expressing concern about the growing cost of prescription drugs and his strong desire in identifying approaches that can make medicine more affordable for California's most at-risk consumers. In the letter, he also encouraged the Bush Administration to aggressively pursue its discussions to achieve fairer pricing of pharmaceuticals in the international marketplace and an equitable distribution of the costs of drug research and development. **(Attachment J)**

In an effort to do this, the Governor put forward "California Rx" that seeks to provide assistance to these Californians. The proposal would establish a drug discount program for low-income uninsured residents through a state contract with a Pharmacy Benefit Manager (PBM). The intent is for Californians that lack insurance would be able to present this discount card at their local pharmacy to receive a discount on their prescription drugs. The PBM would negotiate discounted prices with drug manufacturers for program participants. The program would be available to low-income seniors and uninsured Californians up to 300% of the federal poverty level ($47,000 for a family of three) to secure meaningful discounts in prescription drug costs.

There was general discussion regarding "California Rx". The board was strongly encouraged to take an active role in the development of this proposal and asked that it be discussed at the October board meeting. It was noted that while a bill hasn't been introduced, the information will be provided as part of the Legislative/Regulation Committee's report and would be included if a bill is introduced next year. The board is very sensitive to this issue and is tasked with balancing consumer access to affordable prescriptions against the safety and effectiveness of drugs obtained from foreign sources, and the importance of the Governor's proposal to improve that access through "California Rx" as alternative to importation. **(Attachment K)**

The Senate Health and Human Services Committee held on an informational hearing on the Administration's proposal. The hearing included an in-depth overview of "California Rx", the timeline for implementation, and the estimated cost savings. Representatives were invited to present a critical analysis of the proposal, its feasibility and overall benefit when compared to some of the drug importation proposals that were introduced over the past legislative session.

Implementation of SB 151 – Changes to the Prescribing and Dispensing of Controlled Substances

More questions and answers were provided on the implementation of SB 151 and the changes to the law regarding the prescribing and dispensing of controlled substances. These questions have also been added to the board's Web site. **(Attachment L)**

Routine Compliance Inspections and Citation and Fine Program

Supervising Inspector Dennis reported that in July 2001, the board reinstated its routine inspection program with the goal of inspecting every pharmacy within 3 years. The compliance team will meet this goal by June 30, 2005. Although the team has done a tremendous effort within existing resources to meet the three-year goal, the projections did not take into consideration the licensure of approximately 600 new pharmacies a year or the implementation of the sterile compounding program for which the board did not receive new inspector positions. The compliance team plans to inspect over 1,500 pharmacies by the end of this fiscal year.

Citation and Fine Program

For the period of May 1, 2001 – September 21, 2004, the board has issued 1,843 citation and fines. Of these, 135 citations with fines totaling over $300,000 have not been collected. This is approximately 7% of the total number of citations issued and 20% of the fines. A large number of these citations are issued to cancelled/unlicensed pharmacy technicians, unlicensed premises and cancelled premises. Often times, the citations and fines are issued so that a public record is made, understanding that is more than likely that the fine may not be collected. Staff advised the committee that it is exploring options on the collection of these unpaid fines. **(Attachment M)**

New DEA Controlled Substances Registration Forms

The Enforcement Committee was given a letter from the DEA advising that as of October 1, it will change the style and appearance of the registration certificate. It will consist of two parts: one that can be displayed on the wall and a smaller wallet size version. The certificate will have an embedded watermark logo, to provide authentication and to deter counterfeiting. The DEA asked that this information be shared with licensees and will appear in the board's next newsletter. **(Attachment N)**

Enforcement Committee Meeting Summary of September 29, 2004 (Attachment 0)

Enforcement Team Meeting Summary of September 29, 2004 (Attachment P)

Report on Enforcement Actions (Attachment Q)

Report on Committee Strategic Objectives for 2004/2005 (Attachment R)

ATTACHMENT A

State of California Department of Consumer Affairs

Memorandum

To: Enforcement Committee Date: September 15, 2004

From: Paul Riches
Chief of Legislation and Regulation

Subject: Pharmacists Recovery Program

Attached is a draft proposal for updating statutory provisions related to the Pharmacists Recovery Program (program). Most of the proposed changes are minor, technical revisions to more closely conform the statute to the current operation of the program. However, some of the changes offer substantive changes to the existing program. The following summarizes the changes offered in each section.

Section 4360 – The changes add a directive to operate the program and clarifies that the board may allow intern pharmacists to participate in the program.

Section 4361 – The changes eliminate unnecessary definitions.

Section 4362 – Recasts the provisions specifying who is eligible to enter the program and the terms of entry into the program. First, a licensee can be referred to the program instead of or in addition to disciplinary action. Second, a licensee can enter the program voluntarily. This largely reflects current operation of the program.

The substantial change made is that licensees that enter the program voluntarily will not have their identities withheld from the board. Current law indicates that such "self-referrals" are confidential and the board is generally not informed of their identities. This "confidentiality" can be voided if the program administrator believes the licensee may present a threat to the public. However, participants sign disclosure agreement upon entering the program that permits the program to release their identity to the board. This statutory change would conform to existing practice by the program.

The draft proposes a instead to prohibit the board from taking enforcement action against the self referred licensee based on their entry into the program or any information obtained from the licensee while participating in the program. This change more closely mirrors the diversion programs operated by other boards in the department. The proposal does allow the board to take an enforcement action against a licensee in the program if the board independently obtains information supporting such an action.

Section 4363 – This section is repealed to conform with the treatment of self referred participants discussed above.

Section 4364 – The changes in this section are largely technical and allow the board to adopt criteria for participation outside of the rulemaking process.

Section 4365 – The changes are technical in nature.

Section 4366 – The changes are largely technical and several provisions are relocated to this section.

Section 4367 – This section is repealed. Specifying a staff position in statute is unnecessary. The board may do this through its internal personnel process.

Section 4368 – This section is repealed. The board has not entered into such a contract with a professional association for over five years. Given the current fiscal constraints on the board, it is unlikely that such a contract would be reestablished in the foreseeable future and removing the statutory mandate would seem appropriate. The board can use other means to educate licensees about the availability of the program. The board could enter into such a contract, if it desired, without the statutory mandate.

Section 4369 – This section recasts existing provisions related to terminating a participant from the program.

Section 4370 – This section is repealed. This section specified procedures for self referred licensees. However, it is unnecessary based on the changes proposed in Section 4362 which treat participants similarly regardless of their method of entering the program.

Section 4371 – The changes to this section are largely technical and conform the section to the change in handling of self referred participant information proposed in Section 4362.

Section 4372 – The changes are largely technical and clarifying in nature.

Section 4373 – The changes are technical and conform to the elimination of "volunteer intervenor" and "contracting professional association" in other sections.

Board of Pharmacy
Draft Changes for the Pharmacists Recovery Program

Section 4360 of the Business and Professions Code is amended to read:

4360. ~~It is the intent of the Legislature that the~~ The board ~~seek ways and means to~~ shall operate a pharmacists recovery program to ~~identify and~~ rehabilitate pharmacists and intern pharmacists whose competency may be impaired due to abuse of alcohol, ~~and other drugs~~ drug use, or ~~due to~~ mental illness. The intent of the pharmacists recovery program is to return ~~, so that~~ these pharmacists and pharmacist interns ~~may be treated and returned~~ to the practice of pharmacy in a manner that will not endanger the public health and safety. ~~It is also the intent of the Legislature that the board shall implement this legislation by establishing a diversion program as a voluntary alternative to traditional disciplinary actions.~~

Section 4361 of the Business and Professions Code is amended to read:

4361. As used in this article:

(a) "Participant" means a pharmacist or intern pharmacist who has entered the pharmacists recovery program.
(b) "Pharmacists recovery program" means the rehabilitation program created by this article for pharmacists and intern pharmacist.

~~(a) "Diversion program" means a rehabilitation program designed and administered by a contracting Employee Assistance Program, available to the board in conjunction with, or as an alternative to, other traditional sanctions that the board may impose upon pharmacists pursuant to disciplinary actions within its jurisdiction.~~
~~(b) "Employee assistance program" means an agency or organization that provides confidential assessments and referral services for persons experiencing problems related to alcohol, drug abuse, or mental illness.~~
~~(c) "Pharmacists recovery program" or "program" means the rehabilitation program created by this article for pharmacists whose competency may be threatened or diminished due to abuse of alcohol or other drugs.~~
~~(d) "Volunteer intervenor" means a pharmacist recruited through a pharmacists' professional association who is available and trained to assist pharmacists seeking the benefits of the pharmacist's recovery program.~~

Section 4362 of the Business and Professions Code is amended to read:

4362. (a) A pharmacist or intern pharmacist may enter the pharmacists recovery program if:
(1) The pharmacist or intern pharmacist is referred by the board instead of or in addition to other means of disciplinary action; or,
(2) The pharmacist or intern pharmacist voluntarily elects to enter the pharmacists recovery program.
(b) A pharmacist or intern pharmacist who enters the pharmacists recovery program pursuant to paragraph (2) of subdivision (a) shall not be subject to discipline or other enforcement action by the board based solely on the pharmacist's or intern pharmacist's entry into the pharmacists recovery program or on information obtained from the pharmacist or intern pharmacist while participating in the program unless the pharmacist or pharmacist intern would pose a threat to the health and safety of the public. However, if the board independently receives information

regarding the conduct of the pharmacist or intern pharmacist such information may serve as a basis for discipline or other enforcement action by the board.

~~The program shall fulfill two distinct functions. It shall serve as a diversion program to which the board may refer licentiates, where appropriate, instead of, or in addition to, other means of disciplinary action, and it shall be a confidential source of treatment for pharmacists who, on a strictly voluntary basis, and without the knowledge of the board, desire to avail themselves of its services.~~

Section 4363 of the Business and Professions Code is amended to read:

4363. ~~The board shall administer this article, provided that the names and all identifying information pertaining to those pharmacists who voluntarily seek the services of the program, apart from the institution of any disciplinary action of the board, shall not be disclosed to the board, except as provided in Sections 4370 and 4371.~~

Section 4364 of the Business and Professions Code is amended to read:

4364. (a) The board shall establish criteria for the participation of pharmacists and intern pharmacist in the pharmacist recovery program.
(b) The board may deny a pharmacist or intern pharmacist who fails to meet the criteria for participation entry into the pharmacists recovery program.
(c) The establishment of criteria for participation in the pharmacists recovery program shall not be subject to the requirements of Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code.

Section 4365 of the Business and Professions Code is amended to read:

4365. The board shall contract with one or more ~~employee assistance programs~~ qualified contractors to administer the ~~pharmacists~~ pharmacists recovery program. ~~statewide. The contractor shall be selected through a competitive bid process, and the contract may be renewed annually.~~

Section 4366 of the Business and Professions Code is amended to read:

4366. The functions of the ~~employee assistance~~ contractor administering the pharmacists recovery program shall include, but are not limited to, the following:
(a) To evaluate those pharmacists and intern pharmacist who request participation in the program. ~~according to the guidelines prescribed by the board~~.
(b) To develop a treatment contract with each participant in the pharmacists recovery program. ~~To review and designate those treatment facilities and services to which pharmacists in the program may be referred.~~
(c) To monitor the compliance of each participant with their treatment contract.
~~To receive and review information concerning a pharmacist's or pharmacist intern's participation in the program.~~
(d) ~~To assist pharmacists' professional associations in publicizing the program.~~
~~(e)~~ To prepare reports ~~to be submitted to~~ as required by the board.
(e) To inform each participant of the procedures followed in the program.
(f) To inform each participant of their rights and responsibilities in the program.
(g) To inform each participant of the possible consequences of noncompliance with the program.

Section 4367 of the Business and Professions Code is repealed.

~~**4367.** The board shall designate a program coordinator whose responsibilities shall include the following:~~
~~(a) To serve as liaison between the board and the employee assistance program.~~
~~(b) To monitor and evaluate the employee assistance program.~~
~~(c) To assist the board enforcement unit in tracking pharmacists referred to the program as part of, or alternative to, disciplinary proceedings.~~

Section 4368 of the Business and Professions Code is repealed.

~~**4368.** The board shall contract with a pharmacists' professional association with statewide representation for the following purposes:~~
~~(a) To coordinate the voluntary participation in the program.~~
~~(b) To recruit volunteer intervenors and to train them.~~
~~(c) To promote the program within the profession and to the public.~~
~~(d) To establish and maintain a 24-hour statewide toll-free telephone "hotline" service.~~
~~(e) To report to the board on these functions.~~

Section 4369 of the Business and Professions Code is amended to read:

4369. (a) ~~The board shall inform, in writing, each pharmacist referred to the employees assistance program as part of a board action of the procedures followed in the program, of the rights and responsibilities of the pharmacist in the program, and of the possible consequences of noncompliance with the program.~~
~~(b)~~ Any failure to comply with the ~~provisions of the~~ treatment contract, determination that the participant is failing to derive benefit from the program, or other requirements of the pharmacists recovery program may result in the termination of the pharmacist's or intern pharmacist's participation in the ~~diversion~~ pharmacists recovery program. The name and license number of a pharmacist or intern pharmacist who is terminated ~~for failure to comply with the provisions of the treatment~~ from the pharmacists recovery program and the basis for the termination shall be reported to the board.
~~(c)~~ (b) Participation in ~~a~~ the pharmacists recovery program ~~under this article~~ shall not be a defense to any disciplinary action that may be taken by the board.
(c) ~~Further, no~~ No provision of this article shall preclude the board from commencing disciplinary action against a licensee who is terminated from the pharmacists recovery program. ~~a program under this article.~~

Section 4370 of the Business and Professions Code is repealed.

4370. ~~(a) The employee assistance program shall inform, in writing, each pharmacist who voluntarily participates in the diversion program without referral by the board of the procedures followed in the program, the rights and responsibilities of the pharmacist in the program, the possible consequences of noncompliance with the program.~~
~~(b) The board shall be informed of the pharmacist's noncompliance with the treatment program if the employee assistance program determines that the pharmacist's resuming the practice of pharmacy would pose a threat to the health and safety of the public. The board shall be informed of the basis for the pharmacist's termination and of the determination that the pharmacist's resuming the practice of pharmacy would pose a threat to the health and safety of the public.~~
~~(c) Participation in a program under this article shall not be a defense to any disciplinary action that may be taken by the board. Further, no provision of this article shall preclude the board from commencing disciplinary action against a licensee who is terminated from a program under this article.~~

Section 4371 of the Business and Professions Code is amended to read:

4371. The board shall review the ~~activities of the employee assistance~~ pharmacists recovery program on a quarterly basis. As part of this evaluation, the board shall review files of all participants in the ~~diversion~~ pharmacists recovery program. ~~Names of those pharmacists who entered the program voluntarily without the knowledge of the board shall remain confidential from the board except when monitoring by the board reveals misdiagnosis, case mismanagement, or noncompliance by the participant.~~

Section 4372 of the Business and Professions Code is amended to read:

4372. All board records and records of the ~~employee assistance~~ pharmacists recovery program pertaining to the treatment of a pharmacist or intern pharmacist in the program shall be kept confidential and are not subject to discovery, ~~or~~ subpoena, or disclosure pursuant to Chapter 3.5 of Division 7 of the Government Code (commencing with Section 6250). However, board records and records of the ~~employee assistance~~ pharmacists recovery program may be disclosed and testimony provided in connection with participation in the pharmacists recovery program ~~pursuant to Section 4369 or 4370~~, but only to the extent those records or testimony are relevant to the conduct for which the pharmacist or intern pharmacist was terminated from the pharmacists recovery program.

Section 4373 of the Business and Professions Code is amended to read:

4373. No member of the ~~board or the contracting professional association or any volunteer intervenor~~ shall be liable for any civil damages because of acts or omissions that may occur while acting in good faith pursuant to this article.

State of California **Department of Consumer Affairs**

Memorandum

To: **Enforcement Committee** **Date: November 26, 2003**

From: **Anne Sodergren**
Board of Pharmacy

Subject: **Overview of the Pharmacists Recovery Program**

Background

In 1985, legislation became effective creating the Pharmacists Recovery Program (PRP). This legislation requires the board to seek way and means to identify and rehabilitate pharmacists whose competency may be impaired due to the abuse of alcohol or other drugs, or due to mental illness, so that pharmacists and interns so afflicted may be treated and returned to the practice of pharmacy in a manner which will not endanger the public health and safety. The law requires the board to contract with one or more employee assistance programs to administer the PRP and to contract with a pharmacist's professional association to perform outreach and promote voluntary access to the program.

As required by statute, the program fulfills two distinct functions. The PRP serves as a diversion program to which the board may refer licentiates, where appropriate, either in lieu of or in addition to disciplinary action. The PRP is also a confidential source of treatment for pharmacists who enter the program on a voluntary basis and without the knowledge of the board. Irrespective of the type of referral into the program, all participants are afforded the same treatment opportunities in the PRP.

Board policy is to expedite a pharmacist's the entry into the PRP rather than wait until the completion of an investigation. This is done by an inspector who will refer a pharmacist informally into the PRP. This early intervention assists the licensee in his or her recovery, but more importantly protects the public. Early intervention and referral results in the pharmacist or interns receiving treatment and being monitored while the case is being investigated.

When determining if a participant should be referred to the PRP in lieu of discipline the executive officer considers several factors including:

1. Danger to the public
   a. If drugs were diverted
   b. Quantity of drugs diverted
   c. Injury to consumer
2. Variety and severity of violations
3. Severity of addition or habituation
4. Types of drugs used
5. Frequency and use pattern
6. Prior entrance into the PRP and other mitigating circumstances.

Current Program Overview

For the first time since the PRP's inception, the contract was to a new vendor last July. Along with six other boards and bureaus under the Department of Consumer Affair's Umbrella, the board contracts with Maximus to oversee the Pharmacist Recovery Program. To ensure a seamless transition for the participants, board staff has been working diligently with the new contractor to ensure consistency of care for those in the program.

The general contract requirements for the diversion program are the same for each of the board's with special nuances specific to each board's program. This ensures that all participants in the diversion/recovery programs receive consistent treatment, e.g., inpatient and/or outpatient treatment, health support groups, attendance at AA/NA meetings etc. Several of the boards, utilize Diversion Evaluation Committees (DECs) to monitor participant treatment and compliance in the program as allowed by their specific legislative authority. These meetings can prove costly to the participants who are required to travel to the meetings and also relinquishes the confidentiality and anonymity treatment programs usually adhere to as the participant must appear before the DECs.

The Board of Pharmacy does not have the statutory authority to establish or use DECs. Rather, the board uses a Pharmacy Review Committee (PRC) to review and determine the proper treatment for all board-referred participants (those referred either in addition to or in lieu of formal discipline). The PRC is comprised of the assigned Clinical Case Manager from Maximus, a Supervising Inspector and a staff manager trained in drug recognition and the treatment of substance abuse.

The PRC meets monthly to discuss participants' treatment contracts, compliance and assessment notes as well as to review any participant requests. At minimum each participant's treatment contract and compliance is reviewed on a quarterly basis. However, a participant's treatment contracts may be reviewed more frequently at the participant's request of if the participant is non compliant. All self-referred participants (and board informal) are monitored solely by the Clinical Case Manager therefore ensuring the confidentiality of those participants as required by statute. In the event that a self referred or board informal participant is deemed to be a threat to themselves or to the public, Maximus is required by law to notify the board. This is to ensure that the board's public protection mandate is met.

Ultimately, the board is responsible for public protection first and foremost. While ensuring licensees afflicted with mental illness or chemical dependency are treated and rehabilitated so they can return to the practice of pharmacy safely, this cannot be done at the expense of the board's mandate to protect the public.

Treatment Contracts

All participants entering the PRP are evaluated by a licensed clinician. The initial evaluation identifies the nature and severity of the problem. Initial recommendations are made regarding the treatment and an initial treatment contract is established based on the recommendations.

Rehabilitation plans for a chemically dependent participant typically include total abstinence from alcohol or other mood altering chemicals, inpatient or outpatient treatment, documented attendance 3-5 self-help groups such as Alcoholics Anonymous (AA) and/or Narcotics Anonymous (NA) per week and at least 1-2 support groups. The support groups are conducted under the guidance of a licensed clinician and are comprised of health care professionals in recovery. These support groups serve as a forum for health care professional

to discuss their recovery and may be used to confront a participant who may be acting inappropriately or who is not embracing recovery. A random body fluid testing scheduled is established usually averaging between 24 – 36 urines screens a year (depending on the length of sobriety and severity of the addiction). Failure to maintain sobriety results in the immediate suspension from practice and usually requires at least a 30 - 90 day stay in residential treatment. Upon completion of this residential treatment, outpatient treatment is typically required in addition to support group attendance and attendance at AA and/or NA meetings.

The Pharmacy Review Committee (PRC) will evaluate all board mandated participants progress in the program and determine when it is appropriate for the participant to return to work. The contract will specify the type of pharmacy practice which is acceptable, and any restrictions placed on that participant's practice, e.g. the participant must work with another pharmacist at all times, cannot supervise intern, etc. Prior to returning to work the participant must designate a work site monitor - - typically a pharmacist, who is in a supervisory capacity or at least one management step above the participant. The work site monitor must be aware of the PRP contract and provide regular assessment of the participant's work performance to the PRC members. As a participant continues to gain strength in recovery, the PRC, with approval of the executive officer, will gradually remove the restrictions placed on the pharmacist's practice and reduce the treatment contract requirements by reviewing compliance with the treatment contract, relapse history, if any, and seeking input from the support group leader.

PRP participation is usually a three to five year commitment depending on the severity of the drug abuse or mental illness. The mandatory length of participation must be at minimum one year unless two separate assessments are completed, both of which must conclude that the licensee is not appropriate for diversion. A transition phase, which may begin after at least 24 consecutive months of recovery and a minimum of 24 negative random body fluid tests allows the participant the opportunity to be responsible for his or her own recovery while still in the PRP. A participant who meets all the criteria set by the PRC for completion and who has demonstrated that he or she is a rehabilitated will be successfully completed from the PRP after completing this transition phase and a negative hair test.

About the Participant Population

Since the program inception, 539 pharmacists and interns have received services from the program and 472 participants have been closed out of the program.[1] Approximately 50% of the licensees enrolled in the program are either self-referrals or board informal referrals. Of the participants closed from the program, 109 participants were closed out for either non-compliance or failure to derive benefit. In all circumstances where a participant has been mandated into the program and fails to successfully complete the program, the board will pursue additional disciplinary action. If a participant was a self-referral, the board will also complete an investigation and take appropriate action if the licensee was identified by the contractor as posing a threat to the health and safety of the public.

During the last fiscal year the average age of new participants was between 35 – 54 years old. Practice settings at the time of enrollment for these new participants included 42% in the retail pharmacy, 30% in the hospital pharmacy and the balance working in an assortment of other work settings. Alcohol was the highest reported drug used by these new participants in the previous 12 months prior to enrollment. The other most frequently reported drugs used included Tussionex® (or the generic equivalent), Soma®, Valium®, Heroine®, Hydrocodone, Hydromorphone, Morphine.

Program Statistics[2]

	00/01	01/02[3]	02/03
Enrolled in the Program			
Self	10	9	10
Board Informal	1	2	3
In Lieu Of Discipline	6	14	9
In addition to Discipline	3	0	4
Total Enrolled	20	25	26
Closures from the Program			
Successful Completion	9	10	9
Dismissed Failure to Derive Benefit	1	1	3
Dismissed Non-compliance	5	4	11
Other*	4	3	2
Total Closed	19	18	25
Number of Participants at the end of FY	56	63	63

* Other includes participant death, move to another state, or determined ineligible.

Statistics as reported by Maximus through August 31, 2003. Historical data was provided to Maximus by Managed Health Network, the previous contractor.

[1] Statistics as reported by Managed Health Network
[2] Statistics through May 2002.

ATTACHMENT B

State of California Department of Consumer Affairs

Memorandum

To: Enforcement Committee Date: September 15, 2004

From: Paul Riches
Chief of Legislation and Regulation

Subject: Pharmacy Technician Clean-up

The attached draft of changes to statutes regarding pharmacy technicians and intern pharmacists. Most of the changes are technical and designed to make the statutes more clear. The most significant change is standardizing the terminology relating to the supervision of ancillary personnel. The different code sections used slight variations of language requiring the supervision of ancillary personnel. This draft adopts the most common verbiage of "direct supervision and control" of the pharmacist.

Section 4038 – This change moves the definition from Section 4115.5 to this section for definitions.

Section 4114 – This change applies the standard supervision verbiage to intern pharmacists.

Section 4115 – The changes in this section are mostly technical clean up to eliminate duplicative and unnecessary language. However, one substantive change is made to eliminate the exemption that permits unlicensed personnel to act as a pharmacy technician during their first year of employment at the Department of Corrections, California Youth Authority, Department of Mental Health, Department of Developmental Services or the Department of Veterans Affairs. This provision was added to allow personnel to work in those facilities until they could accumulate enough hours to qualify for licensure as a pharmacy technician. However, experience is no longer a means of qualifying for licensure as a pharmacy technician and this provision is no longer appropriate.

Section 4115.5 – The changes in this section are technical clean-up and conforming to the standard verbiage on supervision of ancillary personnel.

Section 4202 – The changes in this section are technical clean-up.

Board of Pharmacy
Technical Cleanup for Ancillary Personnel

Add Section 4023.5 of the Business and Professions Code, to read:

For the purposes of this chapter "direct supervision and control" means that a pharmacist is on the premises at all times and is fully aware of all activities performed by either a pharmacy technician or intern pharmacist.

Amend Section 4038 of the Business and Professions Code, to read:

4038. (a) "Pharmacy technician" means an individual who assists a pharmacist in a pharmacy in the performance of his or her pharmacy related duties, as specified in Section 4115.
(b) A "pharmacy technician trainee" is a person who is enrolled in a pharmacy technician training program operated by a California public postsecondary education institution or by a private postsecondary vocational institution approved by the Bureau for Private Postsecondary and Vocational Education.

Amend Section 4114 of the Business and Professions Code, to read:

4114. An intern pharmacist may perform any activities pertaining to the practice of pharmacy as the board may determine by regulation. Whenever in this chapter the performance of an act is restricted to a pharmacist, the act may be performed by an intern pharmacist under the direct supervision and control of a pharmacist. The pharmacist shall not supervise more than two intern pharmacists at any one time.

Section 4115 of the Business and Professions Code is amended to read:

4115. (a) ~~Notwithstanding any other provision of law, a~~ A pharmacy technician may perform packaging, manipulative, repetitive, or other nondiscretionary tasks, only while assisting, and while under the direct supervision and control of~~,~~ a pharmacist.
(b) This section does not authorize the performance of any tasks specified in subdivision (a) by a pharmacy technician without a pharmacist on duty. ~~, nor does this section authorize the use of a pharmacy technician to perform tasks specified in subdivision (a) except under the direct supervision and control of a pharmacist.~~
(c) This section does not authorize a pharmacy technician to perform any act requiring the exercise of professional judgment by a pharmacist.
(d) The board shall adopt regulations to specify tasks pursuant to subdivision (a) that a pharmacy technician may perform under the ~~direct~~ supervision ~~and control~~ of a pharmacist. Any pharmacy that employs a pharmacy technician ~~to perform tasks specified in subdivision (a)~~ shall do so in conformity with the regulations adopted by the board ~~pursuant to this subdivision~~.
(e) ~~(1)~~ No person shall act as a pharmacy technician without first being ~~registered with~~ licensed by the board as a pharmacy technician ~~as set forth in Section 4202~~.
~~(2) The registration requirements in paragraph (1) and Section 4202 shall not apply during the first year of employment for a person employed or utilized as a pharmacy technician to assist in the filling of prescriptions for an inmate of a correctional facility of the Department of the Youth Authority or the Department of Corrections, or for a person receiving treatment in a facility operated by the State Department of Mental Health, the State Department of Developmental Services, or the Department of Veterans Affairs.~~
(f) ~~(1) The performance of duties by a pharmacy technician shall be under the direct supervision and control of a pharmacist. The pharmacist on duty shall be directly responsible for the conduct of a pharmacy technician. A pharmacy technician may perform the duties, as specified in~~

~~subdivision (a), only under the immediate, personal supervision and control of a pharmacist. Any pharmacist responsible for a pharmacy technician shall be on the premises at all times, and the pharmacy technician shall be within the pharmacist's view. A pharmacist shall indicate verification of the prescription by initialing the prescription label before the medication is provided to the patient, or by engaging in other verification procedures that are specifically approved by board regulations.~~

~~(2) This subdivision shall not apply to a person employed or utilized as a pharmacy technician to assist in the filling of prescriptions for an inpatient of a hospital or for an inmate of a correctional facility. Notwithstanding the exemption in this subdivision, the requirements of subdivisions (a) and (b) shall apply to a person employed or utilized as a pharmacy technician to assist in the filling of prescriptions for an inpatient of a hospital or for an inmate of a correctional facility.~~

~~(g)~~ (1) A pharmacy with only one pharmacist shall have no more than one pharmacy technician performing the tasks specified in subdivision (a). The ratio of pharmacy technicians performing the tasks specified in subdivision (a) to any additional pharmacist shall not exceed 2:1, except that this ratio shall not apply to personnel performing clerical functions pursuant to Section 4116 or 4117. This ratio is applicable to all practice settings, except for an inpatient of a licensed health facility, a patient of a licensed home health agency, as specified in paragraph (2), an inmate of a correctional facility of the Department of the Youth Authority or the Department of Corrections, and for a person receiving treatment in a facility operated by the State Department of Mental Health, the State Department of Developmental Services, or the Department of Veterans Affairs.

(2) The board may adopt regulations establishing the ratio of pharmacy technicians performing the tasks specified in subdivision (a) to pharmacists applicable to the filling of prescriptions of an inpatient of a licensed health facility and for a patient of a licensed home health agency. Any ratio established by the board pursuant to this subdivision shall allow, at a minimum, at least one pharmacy technician for a single pharmacist in a pharmacy and two pharmacy technicians for each additional pharmacist, except that this ratio shall not apply to personnel performing clerical functions pursuant to Section 4116 or 4117.

(3) A pharmacist scheduled to supervise a second pharmacy technician may refuse to supervise a second pharmacy technician if the pharmacist determines, in the exercise of his or her professional judgment, that permitting the second pharmacy technician to be on duty would interfere with the effective performance of the pharmacist' s responsibilities under this chapter. A pharmacist assigned to supervise a second pharmacy technician shall notify the pharmacist in charge in writing of his or her determination, specifying the circumstances of concern with respect to the pharmacy or the pharmacy technician that have led to the determination, within a reasonable period, but not to exceed 24 hours, after the posting of the relevant schedule. No entity employing a pharmacist may discharge, discipline, or otherwise discriminate against any pharmacist in the terms and conditions of employment for exercising or attempting to exercise in good faith the right established pursuant to this paragraph.

~~(h)~~ (g) Notwithstanding subdivisions (a) and (b) ~~and (f)~~, the board shall by regulation establish conditions to permit the temporary absence of a pharmacist for breaks and lunch periods pursuant to Section 512 of the Labor Code and the orders of the Industrial Welfare Commission without closing the pharmacy. During these temporary absences, a pharmacy technician may, at the discretion of the pharmacist, remain in the pharmacy but may only perform nondiscretionary tasks. The pharmacist shall be responsible for a pharmacy technician and shall review any task performed by a pharmacy technician during the pharmacist's temporary absence. Nothing in this subdivision shall be construed to authorize a pharmacist to supervise pharmacy technicians in greater ratios than those described in subdivision (g).

(h) The pharmacist on duty shall be directly responsible for the conduct of a pharmacy technician supervised by that pharmacist.

(i) A pharmacist shall indicate verification of the prescription by initialing the prescription label before the medication is provided to the patient, or by engaging in other verification procedures that are specifically approved by board regulations.

Section 4115.5 of the Business and Professions Code is amended to read:

4115.5. (a) Notwithstanding any other provision of law, a pharmacy technician trainee ~~student~~ may be placed in a pharmacy ~~as a pharmacy technician trainee~~ to complete an externship for the purpose of obtaining practical training required to become ~~that is required by the board as a condition of becoming~~ ~~registered~~ licensed as a pharmacy technician. ~~A "pharmacy technician student" is a person who is enrolled in a pharmacy technician training program operated by a California public postsecondary education institution or by a private postsecondary vocational institution approved by the Bureau for Private Postsecondary and Vocational Education.~~

(b) (1) A pharmacy technician trainee participating in an externship as described in subdivision (a) may perform the duties described in subdivision (a) of Section 4115 only under the ~~immediate, personal~~ direct supervision and control of a pharmacist. ~~A pharmacist supervising a pharmacy technician trainee shall be on the premises and have the trainee within his or her view at any time the trainee performs the duties described in subdivision (a) of Section 4115.~~

(2) A pharmacist supervising a pharmacy technician trainee participating in an externship as described in subdivision (a) shall be directly responsible for the conduct of the trainee.

(3) A pharmacist supervising a pharmacy technician trainee participating in an externship as described in subdivision (a) shall verify any prescription prepared by the trainee under supervision of the pharmacist by initialing the prescription label before the medication is disbursed to a patient or by engaging in other verification procedures that are specifically approved by board regulations..

(4) ~~No more than one pharmacy technician trainee per pharmacist may participate in an externship as described in subdivision (a) under the immediate, personal supervision and control of that pharmacist at any time the trainee is present in the pharmacy.~~
A pharmacist may only supervise one pharmacy technician trainee at any given time.

(5) A pharmacist supervising a pharmacy technician trainee participating in an externship as described in subdivision (a) shall certify attendance for the pharmacy technician trainee and certify that the pharmacy technician trainee has met the educational objectives established by California public postsecondary education institution or the private postsecondary vocational institution in which the trainee is enrolled, as established by the institution.

(c) (1) Except as described in paragraph (2), an externship in which a pharmacy technician trainee is participating as described in subdivision (a) shall be for a period of no more than 120 hours.

(2) When an externship in which a pharmacy technician trainee is participating as described in subdivision (a) involves rotation between a community and hospital pharmacy for the purpose of training the student in distinct practice settings, the externship may be for a period of up to 320 hours. No more than 120 of the 320 hours may be completed in a community pharmacy setting or in a single department in a hospital pharmacy.

(d) An externship in which a pharmacy technician trainee may participate as described in subdivision (a) shall be for a period of no more than six consecutive months in a community pharmacy and for a total of no more than 12 months if the externship involves rotation between a community and hospital pharmacy. The externship shall be completed while the trainee is enrolled in a course of instruction at the institution.

(e) A pharmacy technician trainee participating in an externship as described in subdivision (a) shall wear identification that indicates his or her trainee ~~student~~ status.

Section 4202 of the Business and Professions Code is amended to read:

4202. (a) ~~An applicant for a pharmacy technician license shall be issued a certificate of registration~~ The board may issue a pharmacy technician license to an individual if he or she is a high school graduate or possesses a General Education Development ~~general education development~~ equivalent, and meets any one of the following requirements:

(1) Has obtained an associate's degree in pharmacy technology.

(2) Has completed a course of training specified by the board.

(3) Has graduated from a school of pharmacy ~~accredited by the American Council on Pharmaceutical Education or a school of pharmacy~~ recognized by the board. Once licensed as a pharmacist, the pharmacy technician license ~~registration~~ is no longer valid and the pharmacy technician license ~~certificate of registration~~ must be returned to the board within 15 days.

(4) Is certified by the Pharmacy Technician Certification Board.

(b) The board shall adopt regulations pursuant to this section for the licensure ~~registration~~ of pharmacy technicians and for the specification of training courses as set out in paragraph (2) of subdivision (a). Proof of the qualifications of any applicant for ~~registration~~ licensure as a pharmacy technician shall be made to the satisfaction of the board and shall be substantiated by any evidence required by the board.

(c) The board shall conduct a criminal background check of the applicant to determine if an applicant has committed acts that would constitute grounds for denial of licensure ~~registration~~, pursuant to this chapter or Chapter 2 (commencing with Section 480) of Division 1.5.

(d) The board may suspend or revoke a ~~registration~~ license issued pursuant to this section on any ground specified in Section 4301.

ATTACHMENT C

State of California Department of Consumer Affairs

Memorandum

To: Enforcement Committee Date: September 16, 2004

From: Paul Riches
Chief of Legislation and Regulation

Subject: Letters of Admonishment

Below is a revision of Section 4315 which authorizes the executive officer of the board to issue a letter of admonishment for a violation of the Pharmacy Law. This section was added last year to provide the board with a broader range of enforcement options. One requirement in the new section is that the licensee receiving the Letter of Admonishment must keep a copy of that letter in the pharmacy for three years. This requirement is problematic for licensees that do not work regularly in the same pharmacy or do not work in a pharmacy at all (exemptee, wholesaler, etc.). Accordingly, staff is recommending the elimination of this requirement.

Section 4315 of the Business and Professions Code is amended to read:

4315. (a) The executive officer, or his or her designee, may issue a letter of admonishment to a licensee for failure to comply with this chapter or regulations adopted pursuant to this chapter, directing the licensee to come into compliance.
(b) The letter of admonishment shall be in writing and shall describe in detail the nature and facts of the violation, including a reference to the statutes or regulations violated.
(c) The letter of admonishment shall inform the licensee that within 30 days of service of the order of admonishment the licensee may do either of the following:

(1) Submit a written request for an office conference to the executive officer of the board to contest the letter of admonishment.

(A) Upon a timely request, the executive officer, or his or her designee, shall hold an office conference with the licensee or the licensee's legal counsel or authorized representative. Unless so authorized by the executive officer, or his or her designee, no individual other than the legal counsel or authorized representative of the licensee may accompany the licensee to the office conference.
(B) Prior to or at the office conference the licensee may submit to the executive officer declarations and documents pertinent to the subject matter of the letter of admonishment.
(C) The office conference is intended to be an informal proceeding and shall not be subject to the provisions of the Administrative Procedure Act (Chapter 3.5 (commencing with Section 11340), Chapter 4 (commencing with Section 11370), Chapter 4.5 (commencing with Section 11400), and Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code).
(D) The executive officer, or his or her designee, may affirm, modify, or withdraw the letter of admonishment. Within 14 calendar days from the date of the office conference, the executive officer, or his or her designee, shall personally serve or send by certified

mail to the licensee's address of record with the board a written decision. This decision shall be deemed the final administrative decision concerning the letter of admonishment.

(E) Judicial review of the decision may be had by filing a petition for a writ of mandate in accordance with the provisions of Section 1094.5 of the Code of Civil Procedure within 30 days of the date the decision was personally served or sent by certified mail. The judicial review shall extend to the question of whether or not there was a prejudicial abuse of discretion in the issuance of the letter of admonishment.

(2) Comply with the letter of admonishment and submit a written corrective action plan to the executive officer documenting compliance. If an office conference is not requested pursuant to this section, compliance with the letter of admonishment shall not constitute an admission of the violation noted in the letter of admonishment.

(d) The letter of admonishment shall be served upon the licensee personally or by certified mail at the licensee's address of record with the board. If the licensee is served by certified mail, service shall be effective upon deposit in the United States mail.

(e) ~~The licensee shall maintain and have readily available on the pharmacy premises a copy of the letter of admonishment and corrective action plan for at least three years from the date of issuance of the letter of admonishment.~~

(~~f~~) Nothing in this section shall in any way limit the board's authority or ability to do either of the following:

(1) Issue a citation pursuant to Section 125.9, 148, or 4067 or pursuant to Section 1775, 1775.15, 1777, or 1778 of Title 16 of the California Code of Regulations.

(2) Institute disciplinary proceedings pursuant to Article 19 (commencing with Section 4300).

ATTACHMENT D

State of California Department of Consumer Affairs

Memorandum

To: Enforcement Committee Date: September 16, 2004

From: Paul Riches
Chief of Legislation and Regulation

Subject: Pharmacist Identification

Senate Bill 1913 amends Section 4115 to permit the board to allow the use of electronic technologies to satisfy the requirement that a pharmacist sign off on prescriptions filled by pharmacy technicians. The regulation text below allows the use of electronic methods of identifying the reviewing pharmacist.

§1712. Use of Pharmacist Identifiers.

(a) Any requirement in this division for a pharmacist to initial or sign a prescription record or prescription label can be satisfied by recording the identity of the reviewing pharmacist in a computer system by a secure means. The computer used to record the reviewing pharmacist's identity shall not permit such a record to be altered after it is made.[1]
(b) The record of the reviewing pharmacist's identity made in a computer system pursuant to subdivision (a) shall be immediately retrievable in the pharmacy.

Note:

Authority cited: Sections 4005, Business and Professions Code. Reference: Sections 4005 and 4115, Business and Professions Code.

[1] This provision was approved by the board at its July 2004 meeting. SB 1913 contains a statutory provision authorizing this regulation.

§1717. Pharmaceutical Practice.

(a) No medication shall be dispensed on prescription except in a new container which conforms with standards established in the official compendia.
Notwithstanding the above, a pharmacist may dispense and refill a prescription for non-liquid oral products in a clean multiple-drug patient medication package (patient med pak), provided:

(1) a patient med pak is reused only for the same patient;
(2) no more than a one-month supply is dispensed at one time; and
(3) each patient med pak bears an auxiliary label which reads, "store in a cool, dry place."

(b) In addition to the requirements of Section 4036, Business and Professions Code, the following information shall be maintained for each prescription on file and shall be readily retrievable:

(1) The date dispensed, and the name or initials of the dispensing pharmacist. All prescriptions filled or refilled by an intern pharmacist must also be initialed by the preceptor before they are dispensed.
(2) The brand name of the drug or device; or if a generic drug or device is dispensed, the distributor's name which appears on the commercial package label; and
(3) If a prescription for a drug or device is refilled, a record of each refill, quantity dispensed, if different, and the initials or name of the dispensing pharmacist.
(4) A new prescription must be created if there is a change in the drug, strength, prescriber or directions for use, unless a complete record of all such changes is otherwise maintained.

(c) Promptly upon receipt of an orally transmitted prescription, the pharmacist shall reduce it to writing, and initial it, and identify it as an orally transmitted prescription. If the prescription is then dispensed by another pharmacist, the dispensing pharmacist shall also initial the prescription to identify him or herself. All orally transmitted prescriptions shall be received and transcribed by a pharmacist prior to compounding, filling, dispensing, or furnishing.
Chart orders as defined in Section 4019 of the Business and Professions Code are not subject to the provisions of this subsection.
(d) A pharmacist may furnish a drug or device pursuant to a written or oral order from a prescriber licensed in a State other than California in accordance with Business and Professions Code Section 4005.
(e) No licensee shall participate in any arrangement or agreement, whereby prescriptions, or prescription medications, may be left at, picked up from, accepted by, or delivered to any place not licensed as a retail pharmacy.
However, a licensee may pick up prescriptions at the office or home of the prescriber or pick up or deliver prescriptions or prescription medications at the office of or a residence designated by the patient or at the hospital, institution, medical office or clinic at which the patient receives health care services. The Board may in its sole discretion waive this application of the regulation for good cause shown.
(f) A pharmacist may transfer a prescription for Schedule III, IV or V controlled substances to another pharmacy for refill purposes in accordance with Title 21, Code of Federal Regulations, 1306.26.
Prescriptions for other dangerous drugs which are not controlled substances may also be transferred by direct communication between pharmacists or by the receiving pharmacist's access to prescriptions or electronic files that have been created or verified by a pharmacist at the transferring pharmacy. The receiving pharmacist shall create a written prescription; identifying it as a transferred prescription; and record the date of transfer and the original prescription number. When a prescription transfer is accomplished via direct access by the receiving pharmacist, the receiving pharmacist shall notify the transferring pharmacy of the transfer. A pharmacist at the transferring pharmacy shall then assure that there is a record of the prescription as having been transferred, and the date of transfer. Each pharmacy shall maintain inventory accountability and pharmacist accountability and dispense in accordance with the provisions of Section 1716. Information maintained by each pharmacy shall at least include:

(1) Identification of pharmacist(s) transferring information;
(2) Name and identification code or address of the pharmacy from which the prescription was received or to which the prescription was transferred, as appropriate;
(3) Original date and last dispensing date;
(4) Number of refills and date originally authorized;
(5) Number of refills remaining but not dispensed;
(6) Number of refills transferred.

(g) The pharmacy must have written procedures that identify each individual pharmacist responsible for the filling of a prescription and a corresponding entry of information into an automated data processing system, or a manual record system, and the pharmacist shall create in his/her handwriting or through hand-initializing a record of such filling, not later than the beginning of the pharmacy's next operating day. Such record shall be maintained for at least three years.

Authority cited: Sections 4005, 4075 and 4114, Business and Professions Code. Reference: Sections 4005, 4019, 4027, 4050, 4051, 4052, 4075, 4114, 4116, 4117 and 4342, Business and Professions Code.

ATTACHMENT E

California State Board of Pharmacy
400 R Street, Suite 4070, Sacramento, CA 95814
Phone (916) 445-5014
Fax (916) 327-6308
www.pharmacy.ca.gov

STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

COMMUNITY PHARMACY SELF-ASSESSMENT

(INCLUDING A HOSPITAL PHARMACY THAT DISPENSES PRESCRIPTIONS)

The California Code of Regulations section 1715 requires the pharmacist-in-charge of each pharmacy licensed under section 4037 or 4029 of the Business and Professions Code to complete a self-assessment of the pharmacy's compliance with federal and state pharmacy law. **The assessment shall be performed before July 1 of every odd-numbered year. The pharmacist-in-charge must also complete a self-assessment within 30 days whenever; (1) a new pharmacy permit has been issued, or (2) there is a change in the pharmacist-in-charge. The primary purpose of the self-assessment is to promote compliance through self-examination and education.**

The self-assessment must be competed in entirety and may be completed online, printed and retained in the pharmacy. Do not copy a previous assessment.

Note: If a hospital pharmacy dispenses prescriptions for outpatient use, a Community Pharmacy Self-Assessment must be completed in addition to the Hospital Pharmacy Self-Assessment.

Each self-assessment must be kept on file in the pharmacy for three years after it is performed.

Pharmacy Name: _____

Address: _____ Phone: _____

Ownership: Sole Owner ☐ Partnership ☐ Corporation ☐ LLC ☐
Non-Licensed Owner ☐ Other (please specify) ☐ _____

Permit #: _____ Exp. Date: _____ Other Permit #: _____ Exp. Date: _____

Licensed Sterile Compounding Permit # _____ or Accredited by: _____

DEA Registration #: _____ Exp. Date: _____ Date of DEA Inventory: _____

Hours: *Daily* _____ *Sat* _____ *Sun.* _____ *24 Hours* _____

PIC: _____ RPH # _____ Exp. Date: _____

Pharmacy Staff (pharmacists, intern pharmacists, pharmacy technicians):
(Please use an additional sheet if necessary)

4. _____ RPH # _____ Exp. Date: _____

5. _____ RPH # _____ Exp. Date: _____

6. _____ RPH # _____ Exp. Date: _____

7. _____ RPH # _____ Exp. Date: _____

8. _____ RPH # _____ Exp. Date: _____

9. _____ INT # _____ Exp. Date: _____

10. _____ INT # _____ Exp. Date: _____

11. _____ INT # _____ Exp. Date: _____

12. _____ TCH # _____ Exp. Date: _____

13. _____ TCH # _____ Exp. Date: _____

14. _____ TCH # _____ Exp. Date: _____

15. _____ TCH # _____ Exp. Date: _____

16. _____ TCH # _____ Exp. Date: _____

17. _____ TCH # _____ Exp. Date: _____

18. _____ TCH # _____ Exp. Date: _____

PIC Initials _____

California State Board of Pharmacy
400 R Street, Suite 4070, Sacramento, CA 95814
Phone (916) 445-5014
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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

COMMUNITY PHARMACY & HOSPITAL OUTPATIENT PHARMACY SELF-ASSESSMENT

All references to the California Code of Regulations (CCR) are to Title 16 unless otherwise noted.

Please mark the appropriate box for each question. If "NO", enter an explanation on "CORRECTIVE ACTION OR ACTION PLAN" lines at the end of the section. If more space is needed, you may add additional sheets.

1. Facility

Yes	No	N/A	
☐	☐	☐	The pharmacy has an area suitable for confidential patient consultation. (CCR 1764, 1714)
☐	☐	☐	The pharmacy is secure and only a pharmacist possesses a key. The pharmacy has provisions for effective control against the theft of dangerous drugs and devices. (B&PC 4116, CCR 1714)
☐	☐	☐	The pharmacy is of sufficient size and has an unobstructed area to accommodate the safe practice of pharmacy. (CCR 1714)
☐	☐	☐	The pharmacy premises, fixtures, and equipment is maintained in a clean and orderly condition. (CCR 1714)
☐	☐	☐	The pharmacy sink has hot and cold running water. (CCR 1714)
☐	☐	☐	The pharmacy has a readily accessible restroom. (CCR 1714)
☐	☐	☐	Current board-issued "Notice to Consumers" is posted in public view where it can be read by the consumer, or written receipts containing the required information are provided to the consumers. A written receipt that contains the required information on the notice may be provided to consumers as an alternative to posting the notice in the pharmacy. Additional "Notice to Consumers" in languages other than English may also be posted. (B&PC 4122, CCR 1707.2)
☐	☐	☐	If applicable, a notice of shared electronic prescription files is posted in public view where it can be clearly read by the purchasing public. (CCR 1717.2)
☐	☐	☐	Pharmacists, interns, pharmacy technicians, and pharmacy technician trainees wear nametags, in 18-point type, that contain their name and license status. (B&PC 680, B&PC 4115.5[e], CCR 1793.7[d])
☐	☐	☐	The original board-issued pharmacy license and the current renewal is posted where they may be clearly read by the purchasing public. (B&PC 4032, 4058)
☐	☐	☐	Does the pharmacy compound sterile injectable drugs? (If yes, complete section 23 – "Compounding Sterile Injectable Drugs".)

CORRECTIVE ACTION OR ACTION PLAN: _____

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2. Delivery of Drugs

Yes	No	N/A	
☐	☐	☐	Dangerous drugs and dangerous devices are only delivered to the licensed premise, and signed for and received by a pharmacist. (B&PC 4059.5[a])
☐	☐	☐	A pharmacy may take delivery of dangerous drugs and dangerous devices when the pharmacy is closed and no pharmacist is on duty if all of the following requirements are met: (B&PC 4059.5[f]):
☐	☐	☐	The drugs are placed in a secure storage facility in the same building as the pharmacy (B&PC 4059.5[f][1]);
☐	☐	☐	Only the pharmacist-in-charge or a pharmacist designated by the pharmacist-in-charge has access to the secure storage facility after dangerous drugs or dangerous devices have been delivered (B&PC 4059.5[f][2]);
☐	☐	☐	The secure storage facility has a means of indicating whether it has been entered after dangerous drugs or dangerous devices have been delivered (B&PC 4059.5[f][3]);
☐	☐	☐	The pharmacy maintains written policies and procedures for the delivery of dangerous drugs and dangerous devices to a secure storage facility (B&PC 4059.5[f][4]); and
☐	☐	☐	The agent delivering dangerous drugs and dangerous devices pursuant to this subdivision leaves documents indicating the name and amount of each dangerous drug or dangerous device delivered in the secure storage facility. The pharmacy shall be responsible for the dangerous drugs and dangerous devices delivered to the secure storage facility. The pharmacy shall also be responsible for obtaining and maintaining records relating to the delivery of dangerous drugs and dangerous devices to a secure storage facility. (B&PC 4059.5[f][5])

CORRECTIVE ACTION OR ACTION PLAN: _____

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3. Drug Stock

Yes	No	N/A	
☐	☐	☐	The drug stock is clean, orderly, properly stored, properly labeled and in-date. (B&PC 4342, H&SC 111255, 22CCR 70263[q])

CORRECTIVE ACTION OR ACTION PLAN: _____

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4. Pharmacist-in-Charge (PIC)

Yes No N/A

☐☐☐ The pharmacy has a PIC that is responsible for the daily operation of the pharmacy. (B&PC 4101, 4113, 4305, 4330, CCR 1709, 1709.1)

☐☐☐ The PIC has adequate authority to assure the pharmacy's compliance with laws governing the operation of a pharmacy. (CCR 1709.1[b])

☐☐☐ The PIC has completed a biennial pharmacy self-assessment before July 1 of each odd numbered year. An additional self-assessment will be completed within 30 days if a new permit is issued or a new PIC employed. Each self-assessment will be maintained in the pharmacy for three years. (CCR 1715)

☐☐☐ Is the PIC in charge of another pharmacy?

☐☐☐ If yes, are the pharmacies within 50 driving miles of each other? (CCR 1709.1[c])

Name of the other pharmacy _____

☐☐☐ Any change of PIC is reported by the pharmacy and the departing PIC to the board in writing within 30 days. (B&PC 4101, 4330)

☐☐☐ Is the PIC serving concurrently as the exemptee-in-charge for a wholesaler or veterinary food-animal retailer? (CCR 1709[c])

If yes, name the wholesaler or veterinary food-animal retailer. _____

CORRECTIVE ACTION OR ACTION PLAN: _____

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5. Duties of a Pharmacist

Yes No N/A

☐☐☐ The pharmacist receives a new prescription order from the prescriber, consults with the patient, identifies, evaluates and interprets a prescription, interprets the clinical data in a patient medication record, consults with any prescriber, nurse, health professional or agent thereof, supervises the packaging of drugs, checks the packaging procedure and product upon completion, is responsible for all activities of pharmacy technicians to ensure that all such activities are per formed completely, safely and without risk of harm to patients, performs any other duty which federal or state law or regulation authorizes only a registered pharmacist to perform and performs all functions which require professional judgment. (CCR 1793.1)

☐☐☐ The pharmacist as part of the care provided by a health care facility, a licensed clinic in which there is physician oversight, or a provider who contracts with a licensed health care service plan with regard to the care or services provided to the enrollees of that health care service plan, is performing the following functions, in accordance with policies, procedures, or protocols of that facility, licensed clinic, or health care service plan that were developed by health professionals, including physicians and surgeons, pharmacists and registered nurses. The functions are: ordering

or performing routine drug therapy related patient assessment procedures, ordering drug therapy related laboratory tests, administering drugs or biologicals by injection, adjusting the drug regimen of a patient, and performing moderate or waived laboratory tests. (B&PC 4052)

CORRECTIVE ACTION OR ACTION PLAN: _____

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6. Duties of an Intern Pharmacist

Yes	No	N/A	
☐	☐	☐	The intern pharmacist may perform all the functions of a pharmacist only under the direct supervision of a pharmacist. A pharmacist may supervise **two interns** at any one time. (B&PC 4114, CCR 1726, 1727)
☐	☐	☐	All prescriptions filled or refilled by an intern are, prior to dispensing, checked for accuracy by a licensed pharmacist and the prescription label initialed by the checking pharmacist. (CCR 1717[b][1], CCR 1712)

CORRECTIVE ACTION OR ACTION PLAN: _____

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7. Duties of a Pharmacy Technician

Yes	No	N/A	
☐	☐	☐	Registered pharmacy technicians are performing packaging, manipulative, repetitive, or other nondiscretionary tasks, while assisting and under the direct supervision and control of a pharmacist. (B&PC 4038, 4115, CCR 1793.2)
☐	☐	☐	Pharmacy technician ratio when only one pharmacist is present, is no more than one technician. For each additional pharmacist present the ratio may not exceed 2 technicians for each additional pharmacist. (B&PC 4038, 4115, CCR 1793.7[f])
☐	☐	☐	A pharmacy technician or pharmacy technician trainee wears identification, in 18-point type, that identifies him or her self as a pharmacy technician or pharmacy technician trainee. (B&PC 680, B&PC 4115.5[e], CCR 1793.7[d])
☐	☐	☐	The pharmacy has a job description for the pharmacy technician and written policies and procedures to ensure compliance with technician requirements. (CCR 1793.7[e])

CORRECTIVE ACTION OR ACTION PLAN: _____

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8. Duties of Non-Licensed Personnel

Yes No N/A

☐☐☐ A non-licensed person (clerk/typist) is permitted to type a prescription label or otherwise enter prescription information into a computer record system, and—at the direction of a pharmacist—may request and receive refill authorization. (CCR 1793.3)

☐☐☐ The number of non-licensed personnel supervised by each pharmacist does not interfere with the effective performance of the pharmacist's responsibilities under the Pharmacy Law. (CCR 1793.3[b])

CORRECTIVE ACTION OR ACTION PLAN: _____

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PHARMACY PRACTICE

9. Consultation/Patient Profile/Review of Drug Therapy

Pharmacists provide oral consultation (CCR 1707.2):

Yes No N/A

☐☐☐ whenever the prescription drug has not been previously dispensed to the patient;

☐☐☐ whenever a refill prescription drug is dispensed in a different dosage form, strength, or with new written directions;

☐☐☐ upon request; and

☐☐☐ whenever the pharmacist deems it warranted in the exercise of his or her professional judgment.

☐☐☐ The pharmacy maintains patient profile information including allergies, date of birth or age, gender and other prescription and nonprescription drugs that the patient takes. (CCR 1707.1)

☐☐☐ The pharmacist reviews a patient's drug therapy and medication record prior to consultation. (CCR 1707.3)

☐☐☐ Consultation is performed in a manner that protects the patient's protected health care information and in an area suitable for confidential patient consultation. (Civil Code 56.10, CCR 1714[a])

☐☐☐ Appropriate drug warnings are provided orally or in writing. (B&PC 4074, CCR 1744)

☐☐☐ If prescription medication is mailed or delivered, written notice about the availability of consultation is provided. (CCR 1707.2)

CORRECTIVE ACTION OR ACTION PLAN: _____

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10. Prescription Requirements

Yes	No	N/A	
☐	☐	☐	Prescriptions are complete with all the required information. (B&PC 4040, 4070)
☐	☐	☐	Orally transmitted prescriptions are received and reduced to writing only by a pharmacist or intern pharmacist working under the direction supervision of a pharmacist. (B&PC 4070, CCR 1717)
☐	☐	☐	If a prescription is orally or electronically transmitted by the prescriber's agent, the pharmacist makes a reasonable attempt to verify that the prescriber's agent is authorized to do so, and the agent's name is recorded. (B&PC 4071)
☐	☐	☐	If orally transmitted, the pharmacist who received the prescription is identified by initialing the prescription, and if dispensed by another pharmacist, the dispensing pharmacist also initials the prescription. (CCR 1717)
☐	☐	☐	The security and confidentiality of electronically transmitted prescriptions are maintained. (CCR 1717.4)
☐	☐	☐	Facsimile prescriptions are received only from prescriber's office. (B&PC 4040[c])
☐	☐	☐	Internet prescriptions for patients (human or animal) in this state are only dispensed or furnished pursuant to a prior good faith examination. (B&PC 4067[a])
☐	☐	☐	All written controlled substances prescriptions (schedule II – V) are on California Security Prescription forms. (H&S 11164[a])
☐	☐	☐	All controlled substance prescriptions are valid for six months and are signed and dated by the prescriber. (H&S 11164[a] [1] and H&S 11120[e])

CORRECTIVE ACTION OR ACTION PLAN: _____

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11. Prescription Labeling, Furnishing and Dispensing

Yes	No	N/A	
☐	☐	☐	The prescription label contains all the required information. (B&PC 4076)
☐	☐	☐	Expiration dates of drugs' effectiveness are consistent with those of the manufacturer if the information is required on the original manufacturer's label. (B&PC 4076, CCR 1718.1)
☐	☐	☐	The trade name or generic name and manufacturer of the prescription drug is accurately identified on the label and prescription record. (B&PC 4076, CCR 1717)
☐	☐	☐	Generic substitution is communicated to the patient. (B&PC 4073)

Yes No N/A

☐☐☐ If the prescription is filled by a pharmacy technician, before dispensing the prescription is checked for accuracy by a licensed pharmacist and that pharmacist initials the prescription label. (B&PC 4115, CCR 1793.7, CCR 1712)

☐☐☐ The federal warning label prohibiting transfer of controlled substances is on the prescription container. (21 CFR 290.5)

☐☐☐ Prescriptions are dispensed in a new and child-resistant container, or senior-adult ease-of-opening tested container, or in a non-complying package only pursuant to the prescriber or when requested by the purchaser. (25 USC 1473 section 4[b], 16 CFR 1700.15, CCR 1717)

☐☐☐ Patient package inserts are dispensed with all estrogen and progesterone medications. (21 CFR 310.515, 310.516)

☐☐☐ This pharmacy furnishes dangerous drugs in compliance with B&PC 4126.5 only to a patient pursuant to a prescription, a wholesaler from whom the dangerous drugs were purchased, a manufacturer from whom the drugs were purchased, a licensed wholesaler acting as a reverse distributor, another pharmacy to alleviate a temporary shortage with a quantity sufficient to alleviate the temporary shortage, a health care provider authorized to received drugs, or to another pharmacy of common ownership,

☐☐☐ Controlled substance prescriptions are not filled or refilled more than six months from the date written. (H&S 12000)

CORRECTIVE ACTION OR ACTION PLAN: _____

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12. Refill Authorization

Yes No N/A

☐☐☐ Refill authorization from the prescriber is obtained before refilling a prescription. (B&PC 4063, 4064)

☐☐☐ Refills are documented. (CCR 1717)

☐☐☐ Prescriptions for dangerous drugs or devices are filled without the prescriber's authorization if the prescriber is unavailable to authorize the refill and if, in the pharmacist's professional judgment, failure to refill the prescription might interrupt the patient's ongoing care and have a significant adverse effect on the patient's well-being. (B&PC 4064)

☐☐☐ Refills for Schedule II controlled substances are prohibited. (H&S 11200)

☐☐☐ Refills for Schedule III and IV controlled substance prescriptions are limited to a maximum of 5 times within 6 months, and all refills taken together do not exceed a 120-day supply. (H&S 11200)

CORRECTIVE ACTION OR ACTION PLAN: _____

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13. Quality Assurance and Medication Errors

Yes No N/A

☐☐☐ Pharmacy has established quality assurance program that documents medication errors attributable, in whole or in part, to the pharmacy or its personnel. (B&PC 4125, CCR 1711)

☐☐☐ Pharmacy quality assurance policies and procedures are maintained in the pharmacy and are immediately retrievable. (CCR 1711[c])

☐☐☐ The pharmacist communicates with the patient or patient's agent that a medication error has occurred and the steps required to avoid injury or mitigate the error. (CCR1711[c][2][A], 1711[c][3]

☐☐☐ When a medication error has occurred (drug was administered to or by the patient, or resulted in a clinically significant delay in therapy) the pharmacist communicates to the prescriber that a medication error has occurred. (CCR 1711[c][2][B], 1711 [c][3])

☐☐☐ Investigation of pharmacy medication errors is initiated within two business days from the date the medication error is discovered. (CCR 1711[d])

The record for quality assurance review for a medication error contains: (CCR 1711[e])

☐☐☐ Date, location, and participants in the quality assurance review;

☐☐☐ Pertinent data and other information related to the medication error(s) reviewed;

☐☐☐ Findings and determinations; and

☐☐☐ Recommended changes to pharmacy policy, procedure, systems or processes, if any.

☐☐☐ The record of the quality assurance review is immediately retrievable in the pharmacy and is maintained in the pharmacy for at least one year from the date it was created. (CCR 1711[f])

☐☐☐ Pharmacists are not deviating from the requirements of a prescription except upon the prior consent of the prescriber, and selection of the drug product is in accordance with B&PC 4073 (generic substitution). (CCR 1716)

CORRECTIVE ACTION OR ACTION PLAN: _____

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14. Erroneous or Uncertain Prescriptions / Corresponding Responsibility for Filling Controlled Substance Prescriptions

Yes No N/A

☐☐☐ Before dispensing a prescription that contains any significant error, omission, irregularity, uncertainty, ambiguity or alteration, the pharmacist contacts the prescriber to obtain information needed to validate the prescription. (CCR 1761[a])

Yes No N/A

☐☐☐ Pharmacists are aware of their corresponding responsibility to determine that a prescription written for a controlled substance was issued for legitimate medical purposes only. (H&S 11153)

☐☐☐ Even after conferring with the prescriber, the pharmacist does not dispenses a controlled substance prescription if he or she knows or has objective reason to know that the prescription was not issued for a legitimate medical purpose. (CCR 1761[b])

CORRECTIVE ACTION OR ACTION PLAN: _____

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15. Prescription Transfer

Yes No N/A

☐☐☐ Only pharmacists transfer prescriptions from pharmacy to pharmacy, and records of prescription transfers are kept as required. (CCR 1717[f][1-6])

☐☐☐ Complete and accurate transfer records are kept on each prescription and refill when dispensed by pharmacies sharing a common electronic file. (CCR 1717.1)

a. Schedule III, IV and V Controlled Prescription Transfers

☐☐☐ For the **transferring pharmacy**: the prescription hard copy is pulled and "void" is written on its face. The name of the pharmacy to which the prescription is transferred is written on the back of the voided prescription and all other information is recorded as required. The prescription can be transferred only once unless the pharmacies electronically share a real-time, on-line database, in which case the prescription is transferred up to the maximum refills permitted by law and the prescriber's authorization. (CFR 1306.25, CCR 1717[f])

☐☐☐ For the **receiving pharmacy**: the prescription is reduced to writing by the pharmacist and "transfer" is written on the face of the transferred prescription and all other information is recorded as required. (CCR 1717[f], CFR 1306.26)

CORRECTIVE ACTION OR ACTION PLAN: _____

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16. Confidentiality of Prescriptions

Yes No N/A

☐☐☐ Patient information is maintained to safeguard confidentiality. (Civil Code 5556 et seq.)

☐☐☐ All prescriptions are kept confidential and only disclosed as authorized by law. (CCR1764)

☐☐☐ The pharmacy ensures electronically transmitted prescriptions are received, maintained and transmitted in a secure and confidential manner. (CCR 1717.4)

Yes No N/A

☐☐☐ If electronically transmitted prescriptions are received by an interim storage device (to allow for retrieval at a later time), the pharmacy maintains the interim storage device in a manner to prevent unauthorized access. (CCR 1717.4)

☐☐☐ If pharmacy has established and utilizes common electronic prescription files to maintain required dispensing information, the system shall not permit disclosure of confidential medical information except as authorized by law. (CCR1717.1)

☐☐☐ Destruction or disposal of patient records preserves the confidentiality of the information contained therein. (Civil Code 56.101)

CORRECTIVE ACTION OR ACTION PLAN: _____

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17. Record Keeping Requirements

Yes No N/A

☐☐☐ A completed biennial pharmacy self -assessment is on file in the pharmacy and maintained for three years. (CCR 1715)

☐☐☐ All drug acquisition and disposition records (complete accountability) are maintained for at least three years. These records include:

☐☐☐ Prescription records (CCR 4081[a])

☐☐☐ Purchase Invoices for all prescription drugs (4081[b])

☐☐☐ Biennial controlled substances inventory (21 CFR 1304.11)

☐☐☐ U.S. Official Order Forms (DEA Form-222) (21 CFR 1305.13)

☐☐☐ Power of Attorney for completion of DEA 222 forms (21 CFR 1305.07)

☐☐☐ Theft and Loss Reports (DEA Form 106) (21 CFR 1301.74[c])

☐☐☐ Record documenting return of drugs to wholesaler or manufacturer (CCR 4081)

☐☐☐ Record documenting transfers or sales to other pharmacies, licensees and prescribers (B&PC 4059, 4081, 4105, 4332, CCR 1718)

Hypodermic needle & syringe sales by a pharmacist to a person without a prescription are limited to: (B&PC 4140 –4149)

☐☐☐ Persons known to the pharmacist and the pharmacist has previously been provided with a prescription or other proof of legitimate medical need;

Yes No N/A

☐☐☐ Use on animals, provided the person is known to the pharmacist or the person's identity can be properly established.

☐☐☐ The sale of 10 or fewer hypodermic needles or syringes at any one time to a person 18 or older **only** if the pharmacy is registered in their local county or city with the Disease Prevention Demonstration Project, and complies with the requirements of that project.

☐☐☐ Records stored off-site (only for pharmacies who have obtained a waiver from the Board of Pharmacy to store records off-site) are secure and retrievable within two business days. Records for non-controlled substances are maintained on the licensed premises for at least one year from the date of dispensing. Controlled substances are maintained on the licensed premises for at least two years from the date of dispensing (CCR 1707)

DEA controlled substances inventory:

☐☐☐ Is completed biennially (every two years). Date completed: _____ (21CFR 1304.11[b])

☐☐☐ Schedule II inventory is separate from Schedule 111, IV and V. (21 CFR 1304.04[h][1], 1304.04[h][2])

☐☐☐ Is available for inspection for three years. (CCR 1718)

☐☐☐ Separate Schedule II records are maintained. This includes Schedule II prescriptions, invoices, US official order forms, and inventory records. (CFR 1304.04[h])

☐☐☐ Schedule III-V prescriptions are filed separately from all prescription records or are designated with a red "C." However, the red C requirement is waived if the pharmacy uses an automated data processing or other record keeping system for identification of controlled substances by prescription number and the original prescription documents can be retrieved promptly. (21 CFR 1304.04[h][2])

☐☐☐ Inventories and records for Schedule III-V controlled substances are filed separately or are designated in some manner that makes the required information readily retrievable from ordinary business records. (21CFR 1304.04)

☐☐☐ U.S. Official Order Form (DEA Form-222) is utilized when ordering all schedule II controlled substances. When schedule II controlled substance orders are received by the pharmacy, for each item received, the date and quantity received is indicated on the DEA Form-222. (21CFR1305.09[e])

☐☐☐ When a pharmacy distributes schedule II controlled substances to a DEA registrant (pharmacies, wholesales, manufacturers, prescribers) a DEA Form-222 is prepared by the purchasing pharmacy and provided to the pharmacy selling the schedule II controlled substances. (21 CFR 1305.09[e])

☐☐☐ When the pharmacy distributes Schedule II controlled substances to other DEA registrants, such as those listed above, Copy 2 of the DEA Form-222, is properly completed by the pharmacy selling the controlled substances and that copy is submitted at the end of each month to the DEA regional office. (21 CFR 1305.09[d])

Yes No N/A

☐☐☐ Sales of controlled substances to other pharmacies or prescribers do not exceed five percent of the total number of controlled substances dosage units dispensed per calendar year, otherwise a wholesaler registration is obtained from DEA and from the board. (21 CFR 1307.11[b], Prescription Drug Marketing Act of 1987 [Pub. L. 100-293, Apr. 22,1988] 503. B&PC 4160)

☐☐☐ When dispensed upon an "oral" order for a true emergency, a Schedule II prescription is provided by the prescriber by the 7th day following the transmission of the oral order. If not received, the pharmacy reports failure to provide prescription document to the California Bureau of Narcotic Enforcement within 144 hours of the failure to provide prescription. (H&SC 11167[d])

☐☐☐ The pharmacy generates a controlled substance printout for refills of Schedule III-V prescriptions at least every three days (72 hours) which contains the signature of the dispensing pharmacist, or the pharmacy maintains an alternate system to document the refilling of controlled substance prescriptions that complies with 21 CFR 1306.22.

☐☐☐ Any controlled substances drug loss is reported upon discovery to the DEA and within 30 days of discovery to the Board of Pharmacy. (21 CFR 1301.74[c], CCR 1715.6)

☐☐☐ Do pharmacy staff hand initial prescription records or prescription labels, or

☐☐☐ Does the pharmacy comply with the requirement for a pharmacist to initial or sign a prescription record or prescription label by recording the identity of the reviewing pharmacist in a computer system by a secure means. This computer does not permit the record to be altered after made and the record of the pharmacist's identity made in the computer system is immediately retrievable in the pharmacy. (CCR 1712, 1717[b][1])

☐☐☐ All Schedule II and III controlled substance dispensing data successfully transmitted to CURES by the 18th of each month. (H&SC 11165[d])

CORRECTIVE ACTION OR ACTION PLAN: _____

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18. Oral/Electronic Transmission and Fractionation of Schedule II Controlled Substance Prescriptions

Yes No N/A

☐☐☐ A faxed prescription for a Schedule II controlled substance is dispensed **after** the original written prescription is received from the prescriber. (21 CFR 1306.11[a], H&SC 11164)

☐☐☐ An oral prescription for a schedule II controlled substance for a patient in a licensed skilled nursing facility, licensed intermediate care facility, licensed home health agency or a licensed hospice care is dispensed only **after** the pharmacist has reduced the prescription to writing on a pharmacy-generated prescription form. The licensed facility provides the pharmacy with a copy of the prescriber signed order when available. (21 CFR 1306.11[f], H&SC 11167.5)

☐☐☐ An electronically transmitted order for a Schedule II controlled substance for a patient in a licensed skilled nursing facility, licensed intermediate care facility, licensed home health agency or a licensed hospice care is dispensed after the pharmacist produces, signs and dates the hard copy

prescription on a form of the pharmacy's design. The licensed facility forwards to the dispensing pharmacist a copy of the order signed by the prescriber when available. (21 CFR 1306.11[f], H&SC 11167.5

Yes No N/A

☐☐☐ All prescriptions received, maintained or transmitted by the pharmacy, whether new or refill, received orally, in writing or electronically, are handled to ensure their security, integrity, authenticity and confidentiality. (CCR1717.4)

☐☐☐ Electronic image transmission prescriptions are either received in hard copy or the pharmacy has the capacity to retrieve a hard copy facsimile of the prescription from the pharmacy's computer memory. (1717.4[e])

☐☐☐ All electronically transmitted prescriptions include the name & address of the prescriber, a telephone number for oral confirmation, date of transmission and the name of identity of the recipient. (1717.4[c])

☐☐☐ Prescriptions received into an interim storage device, in addition to the prescription information, record and maintain the date the prescription is entered into the device, the date the prescription is transmitted out of the device and the recipient of the outgoing transmission. (1717.4[d])

☐☐☐ If unable to supply the full quantity, the pharmacist partially fills a Schedule II prescription and is aware that if the remaining portion of the prescription is to be filled, it must be filled within 72 hours. (CFR 1306.13[a])

☐☐☐ The pharmacist maintains records of each partial filling (filled within 30 days from the date of prescription issuance) of an original prescription for a Schedule II controlled substance written for a patient of a skilled nursing facility or a patient diagnosed as "terminally ill". (21 CFR 1306.13[b], CCR 1745)

☐☐☐ The pharmacist, in an a true emergency dispenses a Schedule II controlled substance from a prescription transmitted orally or electronically by a prescriber. If the order is written by the prescriber, the prescription is in ink, signed and dated by the prescriber. If the prescription is orally or electronically transmitted, it must be reduced to hard copy. The prescriber provides a written prescription on a controlled substance form that meets the requirements of H&S 11162.1 by the seventh day following the transmission of the initial order. (21 CFR 1306.11[d], H&SC 11167)

CORRECTIVE ACTION OR ACTION PLAN: _____

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19. Automated Dispensing

Yes No N/A

☐☐☐ The drugs in an automated dispensing unit are properly labeled and identified with at least the following information: name of drug, strength and dosage form, manufacturer and manufacturer's lot number, and expiration date. (21 CFR Part 210, 211, B&PC 4342, H&SC 110105)

For an "automated drug delivery system" located in a skilled or intermediate care facility licensed by the Department of Health Services, the following is required:

Yes No N/A

☐☐☐ Pharmacy and facility have developed policies and procedures to insure safety, accuracy, accountability, security, access, patient confidentiality, and maintenance of the quality, potency, and purity of stored drugs. (H&SC 1261.6[d][1])

☐☐☐ A pharmacist reviews the order and patient's profile prior to the drug being removed. (H&SC 1261.6[e][2])

☐☐☐ Stocking of the automated drug delivery system is done by a pharmacist. (H&SC 1261.6[f])

If the automated drug delivery system utilizes removable pockets, drawers, or similar technology, the stocking system is done outside the facility in a pharmacy and delivered to the facility:

☐☐☐ Drugs are restocked by a pharmacist or by an intern or technician working under the supervision of a pharmacist. (H&SC 1261.6[f][1])

☐☐☐ Removable pockets or drawers are transported between the pharmacy and the facility in a secure tamper-evident container. (H&SC 1261.1[f][2])

CORRECTIVE ACTION OR ACTION PLAN: _____

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20. Repackaging by the Pharmacy

Yes No N/A

☐☐☐ Drugs are repackaged (precounted or poured) in quantities suitable for dispensing to patients of the pharmacy. Such repackaging is performed according to the Current Good Manufacturing Practice (CGMP), and the drugs are properly labeled with at least the following information: name of drug, strength, dosage form, manufacturer's name and lot number, expiration date, and quantity per repackaged unit. (21 CFR Part 210, 211 [CGMP], B&PC 4342, H&SC 110105, 111430)

☐☐☐ A log is maintained for drugs pre-packed for future dispensing. (CCR 1716.2)

☐☐☐ Drugs previously dispensed are re-packaged at the patient's request in compliance with B&PC 4052.7.

CORRECTIVE ACTION OR ACTION PLAN: _____

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21. Refill Pharmacy

Yes No N/A

☐☐☐ Pharmacy processes refills for another California licensed pharmacy (1707.4[a])

If the answer is "yes", name the pharmacy or pharmacies _____

Yes No N/A

☐☐☐ Some or all pharmacy refill orders are processed by another California licensed pharmacy. (1707.4[a])

If the answer is "yes" , name of refilling pharmacy(s) _____

If the answer to both questions above is "no" or "not applicable" go to section 22.

☐☐☐ Originating pharmacy and refill pharmacy have a contract outlining the refill arrangement, or the pharmacies have the same owner. (1707.4[a][1])

☐☐☐ Refill prescription label meets requirements of B&PC 4076 and shows the name and address of the refilling and or originating pharmacy. (1707.4[a][2])

☐☐☐ Patient is provided with written information, either on the prescription label or prescription container that describes which pharmacy to contact for questions. (1707.4[a][3])

☐☐☐ Both pharmacies maintain complete and accurate records or refill. (1707.4[a][4])

☐☐☐ Both pharmacies are responsible for accuracy of the refilled prescription. (1707.4[a][5])

☐☐☐ Originating pharmacy is responsible for consultation, maintenance of a medication profile and reviewing the patient's drug therapy before delivery of each prescription. (1707.4[a][6])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

22. Policies and Procedures

There are written policies and procedures in place for:

Yes No N/A

☐☐☐ The pharmacist's administration of immunizations by injection pursuant to a prescriber's order; (B&PC 4052[a][5][A][iii])

☐☐☐ Action to be taken to protect the public when a licensed individual employed by or with the pharmacy is known to be chemically, mentally, or physically impaired to the extent that it effects his or her ability to practice the profession or occupation authorized by his or her license; (B&PC 4104[a])

☐☐☐ Action to be taken to protect the public when a licensed individual employed by or with the pharmacy is known to have engaged in the theft or diversion or self-use of prescription drugs belonging to the pharmacy; (B&PC 4104[b])

☐☐☐ Oral consultation for discharge medications to an inpatient of a health care facility licensed pursuant to H&SC 1250, or to an inmate of an adult correctional facility or juvenile detention facility; (B&PC 4074, CCR 1707.2[b][3])

Yes No N/A

☐☐☐ Operation of the pharmacy during the temporary absence of the pharmacist for breaks and meal periods including authorized duties of personnel, pharmacist's responsibilities for checking all work performed by ancillary staff, and pharmacist's responsibility for maintaining the security of the pharmacy; (CCR 1714.1[f])

☐☐☐ Assuring confidentiality of medical information if your pharmacy maintains the required dispensing information for prescriptions, other than controlled substances, in a shared common electronic file. (CCR1717.1[e])

☐☐☐ The delivery of dangerous drugs and dangerous devices to a secure storage facility, if the pharmacy accepts deliveries when the pharmacy is closed and there is no pharmacist present. (B&PC 4059.5[f][1])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

23. Compounding Sterile Injectable Drugs

a. Compounding Area for Parenteral Solutions

Yes No N/A

☐☐☐ Pharmacy has a board issued Licensed Sterile Compounding permit or has current accreditation from the Joint Commission on Accreditation of Healthcare Organizations, or other board approved accreditation agency. (B&PC 4127.1(a) and 4127.1[d])

LSC # _____ OR

Name of accreditation agency _____

The pharmacy has a designated area or cleanroom for the preparation of sterile products that has the following:

☐☐☐ An ISO class 5 laminar airflow hood within an ISO class 7 cleanroom; (B&PC 4127.7[a])

☐☐☐ A positive air pressure differential in the cleanroom that is relative to adjacent areas; (B&PC 4127.7[a])

☐☐☐ An ISO class 5 cleanroom (B&PC 4127.7[b]); and

☐☐☐ A barrier isolator that provides an ISO class 5 environment for compounding. (B&PC 4127.7[c])

☐☐☐ The preparation of sterile injectable products is conducted in an environment that meets criteria specified in pharmacy's written policies and procedures. (CCR 1751.01[a])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

b. Facility & Equipment Standards

Yes	No	N/A	
☐	☐	☐	The compounding environment meets criteria specified in pharmacy's written policies and procedures for safe compounding of sterile injectable drugs. (CCR 1751.01[a])
☐	☐	☐	Only those who are properly attired pursuant to (CCR 1751.4) are allowed in the cleanroom. (CCR 1751.01[b])
☐	☐	☐	All equipment used in the designated cleanroom is made of easily cleaned and disinfected material. (CCR 1751[c])
☐	☐	☐	Exterior workbench surfaces and other hard surfaces in the cleanroom, such as walls, floors, ceilings, shelves, tables, and stools are disinfected weekly and after any unanticipated event that could increase risk of contamination (B&PC 1751.01[d])
☐	☐	☐	There are current and appropriate reference materials regarding the compounding of sterile injectable products located in or immediately available to the pharmacy. (CCR 1751.9)

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

c. Policies and Procedures

The pharmacy has written policies and procedures associated with the preparation and dispensing of sterile injectable products and includes: (CCR 1751.02)

Yes	No	N/A	
☐	☐	☐	Compounding, filling, and labeling of sterile injectable compounds;
☐	☐	☐	Labeling of the sterile injectable product based on the intended route of administration and recommended rate of administration;
☐	☐	☐	Equipment and supplies;
☐	☐	☐	Training of staff in preparation of sterile injectable products;
☐	☐	☐	Training of patient and/or caregiver in the administration of compounded sterile injectable products;
☐	☐	☐	Procedures for the handling and disposal of cytotoxic agents;
☐	☐	☐	Quality assurance program; and
☐	☐	☐	Record keeping requirements.

Yes No N/A

☐☐☐ Ingredients and compounding process for each preparation is determined in writing and reviewed by a pharmacist before compounding begins. (CCR 1751.02 [b])

If compounding sterile injectable products from one or more non-sterile ingredients, the pharmacy has written policies and procedures that comply with the following:

☐☐☐ Policies and procedures are immediately available to all compounding personnel and board inspectors (CCR 1751.02 [c][1]); and

☐☐☐ All compounding personnel have read the policies and procedures, any additions, revisions, and deletions before compounding. (CCR 1751.02 [c][2])

Policies and procedures address the following: (CCR 1751.02 [c][3] [A-K])

☐☐☐ Competency evaluation;

☐☐☐ Storage and handling of products and supplies;

☐☐☐ Storage and delivery of final products;

☐☐☐ Process validation;

☐☐☐ Personnel access and movement of materials into and near the controlled area;

☐☐☐ Use and maintenance of environmental control devices used to create the critical area for manipulation of sterile products (i.e., laminar-airflow workstations, biological safety cabinets, class 100 cleanrooms, and barrier isolator workstations;

☐☐☐ A regular cleaning schedule for the controlled area and any equipment in the controlled area and the alternation of disinfectants. Pharmacies subject to an institutional infection control policy may follow that policy as it relates to cleaning schedules;

☐☐☐ Disposal of packaging materials, used syringes, containers, and needles to enhance sanitation and avoid accumulation in the controlled area;

☐☐☐ For sterile batch compounding, written policies and procedures for the use of master formulas and work sheets and for appropriate documentation;

☐☐☐ Sterilization; and

☐☐☐ End-product evaluation and testing.

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

d. Labeling

The pharmacy's compounded sterile injectable product labels contain: (CCR 1751.2)

Yes	No	N/A	
☐	☐	☐	Telephone number of the pharmacy, unless dispensed for a hospital in-patient;
☐	☐	☐	Name and concentrations of ingredients contained in the product;
☐	☐	☐	Instructions for storage and handling; and
☐	☐	☐	A special label which states "Chemotherapy—Dispose of Properly" for all cytotoxic agents.

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

e. Record Keeping Requirements

Yes	No	N/A	
☐	☐	☐	Pharmacy records for sterile injectable products produced for future use (pursuant to section 1716.1), in addition to record requirements of section 1716.2, contain the name, lot number, amount, and date on which the products were provided to a prescriber. (CCR 1751.3[a])
☐	☐	☐	Records for sterile products compounded from one or more non-sterile ingredients are maintained for at least three years and contain the following: (CCR 1751.3[b])
☐	☐	☐	The training and competency evaluation of employees in sterile product procedures;
☐	☐	☐	Refrigerator and freezer temperatures;
☐	☐	☐	Certification of the sterile compounding environment;
☐	☐	☐	Other facility quality control logs specific to the pharmacy's policies and procedures (e.g., cleaning logs for facilities and equipment);
☐	☐	☐	Inspection for expired or recalled pharmaceutical products or raw ingredients; and
☐	☐	☐	Preparation records including the master work sheet, the preparation work sheet, and records of end-product evaluation results.
☐	☐	☐	The pharmacy maintains records of validation processes as required by Section 1751.7(b) for three years. (CCR 1751.3[c])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

f. Attire

Yes	No	N/A	
☐	☐	☐	When preparing cytotoxic agents, gowns and gloves are worn.(CCR 1751.4[a])
☐	☐	☐	When compounding sterile products from one or more non-sterile ingredients and a barrier isolator is not used:
☐	☐	☐	Cleanroom garb is donned and removed outside the designated area; (CCR 1751.4[b][2])
☐	☐	☐	Individuals in the cleanroom wear a low-shedding coverall, head cover, face mask, and shoe covers; (CCR 1751.4[b][1])
☐	☐	☐	No hand, finger, or wrist jewelry is worn or if the jewelry cannot be removed, it is cleaned and covered with a sterile glove; (CCR 1751.4[b][3])
☐	☐	☐	Head and facial hair is kept out of critical area or covered (CCR 1751.4[b][4]); and
☐	☐	☐	Gloves of low-shedding material are worn. (CCR 1751.4[b][5])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

g. Training of Staff, Patient, and Caregiver

Yes	No	N/A	
☐	☐	☐	Consultation is available to the patient and/or primary caregiver concerning proper use of sterile injectable products and related supplies furnished by the pharmacy. (CCR 1751.5[a])
☐	☐	☐	The pharmacist-in-charge ensures that all pharmacy personnel engaging in compounding sterile injectable drug products has training and demonstrated competence in the safe handling of those products, including cytotoxic agents if the pharmacy compounds such agents. (CCR 1751.5[b])
☐	☐	☐	Records of training and demonstrated competence are available for each individual and are retained for three years beyond the employment period. (CCR 1751.5[c])
☐	☐	☐	The pharmacist-in-charge ensures the continuing competence of pharmacy personnel engaged in compounding sterile injectable products. (CCR 1751.5[d])
☐	☐	☐	When compounding sterile products from one or more non-sterile ingredients, the pharmacy complies with the following training requirements: (CCR 1751.5[e]) The pharmacy follows a written program of training and performance evaluation designed to ensure that each person working in the designated area has the knowledge and skills necessary to perform their assigned tasks properly. This program of training and performance evaluation addresses the following: (CCR 1751.5[e][1][A-J])

Yes No N/A

☐☐☐ Aseptic technique;

☐☐☐ Pharmaceutical calculations and terminology;

☐☐☐ Sterile product compounding documentation;

☐☐☐ Quality assurance procedures;

☐☐☐ Proper gowning and gloving technique;

☐☐☐ General conduct in the controlled area;

☐☐☐ Cleaning, sanitizing, and maintaining equipment used in the controlled area;

☐☐☐ Sterilization techniques; and

☐☐☐ Container, equipment, and closure system selection.

☐☐☐ Each person assigned to the controlled area successfully completes practical skills training in aseptic technique and aseptic area practices. (CCR 1751.5[e][2])

☐☐☐ Evaluation includes written testing and a written protocol of periodic routine performance checks involving adherence to aseptic area policies and procedures. (CCR 1751[e][2])

☐☐☐ Each person's proficiency and continuing training is reassessed every 12 months. (CCR 1751[e][2])

☐☐☐ Results of these assessments are documented and retained in the pharmacy for three years. (CCR 1751[e][2])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

h. Disposal of Waste Material

Yes No N/A

☐☐☐ The pharmacy has written policies and procedures for the disposal of infectious material and/or materials containing cytotoxic residues. (CCR 1751.6)

☐☐☐ The procedures include the cleanup of spills and are in conformance with local health jurisdiction. (CCR 1751.6)

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

i. Quality Assurance and Process Validation

Yes No N/A

☐☐☐ There is a documented, ongoing quality assurance program that monitors personnel performance, equipment, and facilities, and the pharmacist-in-charge assures that the end-product meets the required specifications by periodic sampling. (CCR 1751.7[a])

The Quality Assurance Program contains at least the following: (CCR 1751.7[a][1-5])

☐☐☐ Cleaning and sanitization of the parenteral medication preparation area;

☐☐☐ Batch produced sterile injectable drug products compounded from one or more non-sterile ingredients are subject to documented end product testing for sterility and pyrogens and are quarantined until the end product testing confirms sterility and acceptable levels of pyrogens;

☐☐☐ The storage of compounded sterile injectable products in the pharmacy and periodic documentation of refrigerator temperature;

☐☐☐ Steps to be taken in the event of a drug recall; and

☐☐☐ Written justification of the chosen expiration dates for compounded sterile injectable products in accordance with CCR 1716.2[a][3]).

☐☐☐ Each individual involved in the preparation of sterile injectable products successfully completes a validation process on technique before being allowed to prepare sterile injectable products. (CCR 1751.7[b])

☐☐☐ The validation process is carried out in the same manner as normal production, except that an appropriate microbiological growth medium is used in place of the actual product used during sterile preparation. (CCR 1751.7[b])

☐☐☐ The validation process is representative of all types of manipulations, products and batch sizes the individual is expected to prepare. (CCR 1751.7[b])

☐☐☐ The same personnel, procedures, equipment, and materials are involved. (CCR 1751.7[b])

☐☐☐ Completed medium samples are incubated. (CCR 1751.7[b])

☐☐☐ If microbiological growth is detected, the sterile preparation process is evaluated, corrective action taken, and the validation process is repeated. (CCR 1751.7[b])

☐☐☐ Personnel competency is revalidated and documented at least every 12 months, whenever the quality assurance program yields an unacceptable result, when the compounding process changes, equipment used in the compounding of sterile injectable drug products is repaired or replaced, the facility is modified in a manner that affects airflow or traffic patterns, or whatever aseptic techniques are observed. (CCR 1751.7[b])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

j. Reference Materials

Yes No N/A

☐☐☐ Current reference materials are maintained or available to the pharmacy on the drugs and chemicals used in parenteral therapy services and all parenteral therapy manufacturing, dispensing, distribution, and counseling services provided. (CCR 1751.9)

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

24. Compounding Non-Sterile Drug Products

a. Compounding Unapproved Drugs for Prescriber Office Use (CCR 1716.1):

Yes No N/A

☐☐☐ Pharmacy compounds unapproved drugs for prescriber office use based upon a reasonable quantity

☐☐☐ Establishing reasonable quantity is based on the intended use of the compounded medication and nature of the prescriber's practice.

☐☐☐ Compounded medications means medications actively compounded by the pharmacy supplying them to a prescriber.

☐☐☐ Prescriber office use means application or administration in the prescriber's office or for distribution of not more than a 72 hour supply to the prescriber's patients as estimated by the prescriber.

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

b. Record Keeping Requirements – Compounding for Future Furnishing (CCR1716.2)

Yes No N/A

☐☐☐ For the purpose of compounding in quantities larger than required for immediate dispensing by a prescriber or for future dispensing upon prescription, a pharmacy shall maintain records that include, but are not limited to:

☐☐☐ The date of preparation (compounding);

☐☐☐ The name of the manufacturer, the lot number of all components used to compound the product;

☐☐☐ The expiration date of each component (if not available, the source and date of purchase)

Yes No N/A

☐☐☐ A pharmacy lot number or identification number;

☐☐☐ A master formula for each compounded drug product in a readily retrievable form to also include:

☐☐☐ The amount of each component, compounding directions, etc;

☐☐☐ A beyond-use-date not to exceed 180 days or the shortest expiration date of any component (unless the pharmacy possesses stability data for each product compounded by the pharmacy beyond the 180 days);

☐☐☐ The signature/initials of the person(s) who compounded the drug product; and

☐☐☐ The signature/initials of the pharmacist who checked the final product.

☐☐☐ The final quantity of drug product compounded (number of individual units by weight or volume and package size);

☐☐☐ Status/disposition of any quarantined compounded drug products to also include release date; and

☐☐☐ Status/disposition of any compounded drug products that failed to meet standards for quality purity or strength.

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

25. NUCLEAR PHARMACY

Yes No N/A

☐☐☐ All pharmacists handling radioactive drugs are competent in the preparation, handling, storage, receiving, dispensing, disposition and pharmacology of radioactive drugs. (CCR 1708.4)

☐☐☐ A pharmacist qualified under CCR 1708.4 to furnish radioactive drugs is in the pharmacy whenever the furnishing of radioactive drugs occurs. All personnel involved in the furnishing of radioactive drugs are under the immediate and direct supervision of such a qualified pharmacist. (CCR 1708.5)

☐☐☐ The pharmacy possesses a current Sterile Compounding Permit (B&P 4127) and is compliant with CCR 1751. (must also complete section 21)

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

PHARMACIST-IN-CHARGE CERTIFICATION:

I, (Please print) _____, RPH # _____ hereby certify that I have completed the self-assessment of this pharmacy of which I am the pharmacist-in-charge. I understand that all responses are subject to verification by the Board of Pharmacy. I further state under penalty of perjury that the information contained in this self-assessment form is true and correct.

Signature _____ Date _____
(Pharmacist-in-Charge)

Legal References used in the self-assessment forms (California Code of Regulations [CCR], Title 16 and Title 24, and Business and Professions Code [B&PC], Chapter 9, Division 2) can be found in the *California Pharmacy Law* (below) or visit the Board of Pharmacy Web site at www.pharmacy.ca.gov under *California Pharmacy Law and Index.*

The Health and Safety Code (H&SC), Division 10, Uniform Controlled Substances Act is also in the *California Pharmacy Law* (below) or you can visit the Board of Pharmacy Web site at www.pharmacy.ca.gov under *California Pharmacy Law and Index.*

California Code of Regulations (CCR), Chapter 1, Division 5, Title 22, and other references can be found in the California State Law Library or county law libraries.

Code of Federal Regulations (CFR), Title 21, Chapter II, Drug Enforcement Administration, may be found at www.dea.gov.

California Board of Pharmacy
400 R Street, Suite 4070
Sacramento CA 95814
(916) 445-5014
fax: (916) 327-6308
www.pharmacy.ca.gov

California Pharmacy Law
May be obtained by contacting:
Law Tech
1060 Calle Cordillera, Suite 105
San Clements CA 92673
(800) 498-0911 Ext. 74
www.lawtech-pub.com

Pharmacist Recovery Program
(800) 522-9198 (24 hours a day)

Atlantic Associates, Inc. (CURES)
Prescription Collection
8030 S. Willow Street, Bldg. III, Unit 3
Manchester NH 03103
(888) 492-7341

Medical Board of California
1430 Howe Avenue
Sacramento CA 95825
(800) 633-2322
(916) 263-2499
fax: (916) 263-2387
www.medbd.ca.gov

The **Drug Enforcement Administration** may be contacted at:

DEA - Los Angeles
255 East Temple Street, 20th Floor
Los Angeles CA 90012
(213) 894-2216, 2217, 4697, or 6711
(213) 894-4016 (Diversion or Investigation)

DEA – San Francisco
450 Golden Gate Avenue
San Francisco CA 94102
(415) 436-7900
(415) 436-7854 (Theft Reports or Diversion)

DEA - Sacramento
1860 Howe Avenue
Sacramento CA 95825
(916) 566-7160

DEA - Riverside
4470 Olivewood Avenue
Riverside, CA 92501-6210
(909) 328-6200

DEA - Fresno
2444 Main Street, Suite 240
Fresno, CA 93721
(559) 487-5402

DEA – San Diego
4560 Viewridge Avenue
San Diego, CA 92123-1637
(858) 616-4100

DEA – Oakland
1301 Clay Street, Suite 460N
Oakland, CA 94612
(510) 637-5600

DEA – San Jose
One North First Street, Suite 405
San Jose, CA 95113
(408) 291-7235

ATTACHMENT F

California State Board of Pharmacy
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Phone (916) 445-5014
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www.pharmacy.ca.gov

STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

HOSPITAL PHARMACY SELF-ASSESSMENT

The California Code of Regulations section 1715 requires the pharmacist-in-charge of each pharmacy licensed under section 4037 or 4029 of the Business and Professions Code to complete a self-assessment of the pharmacy's compliance with federal and state pharmacy law. **The assessment shall be performed before July 1 of every odd-numbered year. The pharmacist-in-charge must also complete a self-assessment within 30 days whenever (1) a new pharmacy permit has been issued, or (2) there is a change in the pharmacist-in-charge. The primary purpose of the self-assessment is to promote compliance through self-examination and education.**

The self-assessment must be competed in entirety and may be completed online, printed and retained in the pharmacy. Do not copy a previous assessment.

Note: If dispensing prescriptions for outpatient use, a Community Pharmacy Self-Assessment must be completed also.

Each self-assessment must be kept on file in the pharmacy for three years after it is performed.

Pharmacy Name: _____

Address: _____ Phone: _____

Ownership: Sole Owner ☐ Partnership ☐ Corporation ☐ LLC ☐
Non-Licensed Owner ☐ Other (please specify) ☐ _____

Permit #: _____ Exp. Date: _____ Other Permit #: _____ Exp. Date: _____

Licensed Sterile Compounding Permit # _____ or Accredited by: _____

DEA Registration #: _____ Exp. Date: _____ Date of DEA Inventory: _____

Hours: *Daily* _____ *Sat* _____ *Sun.* _____ *24 Hours* _____

PIC: _____ RPH # _____ Exp. Date: _____

Pharmacy staff (pharmacists, interns, technicians):

1. _____ RPH # _____ Exp. Date: _____

2. _____ RPH # _____ Exp. Date: _____

3. _____ RPH # _____ Exp. Date: _____

Pharmacy Staff (continued): (Please use an additional sheet if necessary)

4. _____ RPH # _____ Exp. Date: _____

5. _____ RPH # _____ Exp. Date: _____

6. _____ RPH # _____ Exp. Date: _____

7. _____ RPH # _____ Exp. Date: _____

8. _____ RPH # _____ Exp. Date: _____

9. _____ INT # _____ Exp. Date: _____

10. _____ INT # _____ Exp. Date: _____

11. _____ INT # _____ Exp. Date: _____

12. _____ TCH # _____ Exp. Date: _____

13. _____ TCH # _____ Exp. Date: _____

14. _____ TCH # _____ Exp. Date: _____

15. _____ TCH # _____ Exp. Date: _____

16. _____ TCH # _____ Exp. Date: _____

17. _____ TCH # _____ Exp. Date: _____

18. _____ TCH # _____ Exp. Date: _____

California State Board of Pharmacy
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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

HOSPITAL INPATIENT PHARMACY AND PRACTICE SELF-ASSESSMENT

All references to the California Code of Regulations (CCR) are Title 16 unless otherwise noted.

Please mark the appropriate box for each question. If "NO," enter an explanation on "CORRECTIVE ACTION or ACTION PLAN" lines below. If more space is needed, you may add additional sheets.

1. Pharmacy

Yes	No	N/A	
☐	☐	☐	The pharmacy is secure and has provisions for effective control against the theft of dangerous drugs and devices. (B&PC 4117, CCR 1714)
☐	☐	☐	The pharmacy maintains "night stock" medications which are accessible without entering the pharmacy during hours when the pharmacy is closed, and the pharmacist is not available. Access is limited to designated registered nurses. (22 CCR 70263[n])
☐	☐	☐	The pharmacy is of sufficient size and has an unobstructed area to accommodate the safe practice of pharmacy. (CCR 1714)
☐	☐	☐	The pharmacy premises, fixtures, and equipment are maintained in a clean and orderly condition. (CCR 1714)
☐	☐	☐	The pharmacy sink has hot and cold running water. (CCR 1714)
☐	☐	☐	The pharmacy has a readily accessible restroom. (CCR 1714)
☐	☐	☐	The original board-issued pharmacy license and the current renewal are posted where they may be clearly read by the purchasing public. (B&PC 4032, 4058)
☐	☐	☐	Pharmacists, interns, pharmacy technicians, and pharmacy technician trainees wear nametags, in 18-point type, that contain their name and license status. (B&PC 680, B&PC 4115.5[e], CCR 1793.7[d])
☐	☐	☐	Does the pharmacy compound sterile injectable drugs? (If yes, complete section 24 – "Compounding Sterile Injectable Drugs")

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

2. Nursing Stations

Yes No N/A

☐☐☐ Adequate space is available at ward or nursing station for the storage of drugs and preparation of medication doses. All such spaces and areas can be locked and are accessible to authorized personnel only. (22 CCR 70269)

☐☐☐ The pharmacist is responsible for the monthly inspections of all floor stock and drugs maintained in nursing stations. Any irregularities are reported to the director of nursing services, and as required by hospital policy. (22 CCR 70263[q][10])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

3. Delivery of Drugs

Yes No N/A

☐☐☐ Delivery to the pharmacy of dangerous drugs and dangerous devices are only delivered to the licensed premise and signed for and received by a pharmacist. (B&PC 4059.5[a])

☐☐☐ Deliveries to a hospital pharmacy may be made to a central receiving location within the hospital. However, the dangerous drugs or dangerous devices shall be delivered to the licensed pharmacy premise within one working day following receipt by the hospital, and the pharmacist on duty at that time shall immediately inventory the drugs or devices. (B&PC 4059.5[c])

A pharmacy may take delivery of dangerous drugs and dangerous devices when the pharmacy is closed and no pharmacist is on duty if all of the following requirements are met (B&PC 4059.5[f]):

☐☐☐ The drugs are placed in a secure storage facility in the same building as the pharmacy (B&PC 4059.5[f][1]);

☐☐☐ Only the pharmacist-in-charge or a pharmacist designated by the pharmacist-in-charge has access to the secure storage facility after dangerous drugs or dangerous devices have been delivered (B&PC 4059.5[f][2]);

☐☐☐ The secure storage facility has a means of indicating whether it has been entered after dangerous drugs or dangerous devices have been delivered (B&PC 4059.5[f][3]);

☐☐☐ The pharmacy maintains written policies and procedures for the delivery of dangerous drugs and dangerous devices to a secure storage facility (B&PC 4059.5[f][4]); and

☐☐☐ The agent delivering dangerous drugs and dangerous devices pursuant to this subdivision leaves documents indicating the name and amount of each dangerous drug or dangerous device delivered in the secure storage facility. The pharmacy shall be responsible for the dangerous drugs and dangerous devices delivered to the secure storage facility. The pharmacy shall also be responsible for obtaining and maintaining records relating to the delivery of dangerous drugs and dangerous devices to a secure storage facility. (B&PC 4059.5[f][5])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

4. Drug Stock

Yes No N/A

☐☐☐ The drug stock is clean, orderly, properly stored, properly labeled and in-date. (B&PC 4342, H&SC 111255, 22 CCR 70263[q])

☐☐☐ All ward/floor drug stock and drug supplies that are maintained for access when the pharmacist is not available are properly labeled and stored. (22 CCR 70263[n])

☐☐☐ Preferentially priced drugs are furnished solely or predominately to inpatients in accordance with provisions of the Nonprofit Institutions Act (15 USC 13c). Such drugs also may be dispensed pursuant to prescriptions for inpatients at the time of discharge, for employees of the hospital, or on an emergency basis for a walk-in customer (provided that sales to walk-ins do not exceed one percent of the pharmacy's total prescription sales). (B&PC 4380, CCR 1710)

CORRECTIVE ACTION OR ACTION PLAN: _____

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5. Pharmacist-in-Charge (PIC)

Yes No N/A

☐☐☐ The pharmacy has a PIC who is responsible for the daily operation of the pharmacy. (B&PC 4101, 4113, 4305, 4330, CCR 1709, 1709.1)

☐☐☐ The PIC has adequate authority to assure the pharmacy's compliance with laws governing the operation of a pharmacy (CCR 1709.2[b])

☐☐☐ Is the PIC in charge of another pharmacy?

☐☐☐ If yes, the pharmacies are within 50 driving distance miles of each other. (CCR 1709.1[c])

If yes, name of other pharmacy _____

☐☐☐ Any change of PIC is reported by the pharmacy and the departing PIC to the board in writing within 30 days. (B&PC 4101, 4330)

☐☐☐ Is the PIC serving concurrently as the exemptee-in-charge for a wholesaler or veterinary food-animal retailer? (CCR 1709[c])

If yes, name the wholesaler or veterinary food-animal retailer. _____

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

6. Duties of a Pharmacist

Yes No N/A

☐☐☐ Within the scope of the inpatient pharmacy service, the pharmacist receives a chart order for an inpatient; identifies, evaluates and interprets the chart order; reviews patient's drug regimen and interprets the clinical data in the patient's medication record; consults with any prescriber, nurse or health care professional; calculates drug doses; supervises the packaging of drugs and checks the packaging procedures and products upon completion; is responsible for all activities of pharmacy technicians, interns and clerks related to the furnishing of drugs to ensure that all such activities are performed completely, safely and without risk of harm to patients; performs any other duty which federal or state law or regulation authorizes only a registered pharmacist to perform; and performs all functions which require professional judgment. (B&PC 4051, CCR 1793.1)

☐☐☐ Pharmacists in a licensed health care facility who are performing the following functions are doing so in accordance with the hospital's policies, procedures and protocols which have been developed by health professionals including physicians, pharmacists, and registered nurses, with the concurrence of the facility administrator; ordering or performing routine drug therapy-related patient assessment procedures; ordering drug therapy-related laboratory tests; administering drugs or biologicals by injection; initiating or adjusting the drug regimen of a patient, and/or performing moderate or waived laboratory tests. Prior to performing any of these functions, the pharmacist must have either (1) successfully completed clinical residency training or (2) demonstrated clinical experience in direct patient care delivery as specified in B&PC section 4052(b). (B&PC 4027, 4051, 4052)

CORRECTIVE ACTION OR ACTION PLAN: _____

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7. Duties of an Intern Pharmacist

Yes No N/A

☐☐☐ Intern pharmacists are performing all the functions of a pharmacist only under the direct supervision of a pharmacist, and the pharmacist is supervising no more than **two interns** at any one time. (B&PC 4114, CCR 1726, 1727)

☐☐☐ All prescriptions filled or refilled by an intern are initialed by a pharmacist prior to dispensing. (CCR 1717[b][1])

CORRECTIVE ACTION OR ACTION PLAN: _____

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8. Duties of a Pharmacy Technician

Yes No N/A

☐☐☐ Registered pharmacy technicians are performing packaging, manipulative, repetitive, or other nondiscretionary tasks related to the furnishing of drugs, while assisting and under the direct supervision and control of a pharmacist. (B&PC 4038, 4115, CCR 1793.2)

☐☐☐ The ratio for technicians performing the tasks above, related to the furnishing of drugs to inpatients, does not exceed one pharmacist on duty for two technicians on duty. However, when prescriptions are dispensed to discharge patients with only one pharmacist, there is no more than one technician performing the tasks as defined in B&PC 4115(a). The ratio of pharmacy technicians performing those tasks for additional pharmacists does not exceed 2:1. (B&PC 4038, 4115, CCR 1793.7[f])

Yes No N/A

☐☐☐ Any function performed by a technician in connection with the dispensing of a prescription or chart order, including repackaging from bulk and storage of pharmaceuticals is verified and documented in writing by a pharmacist. (CCR 1793.7)

☐☐☐ A pharmacy technician or pharmacy technician trainee wears identification, in 18-point type that identifies him or her self as a pharmacy technician or pharmacy technician trainee. (B&PC 680, B&PC 4115.5[e], CCR 1793.7[d])

☐☐☐ The pharmacy has a job description for the pharmacy technician and written policies and procedures to ensure compliance with the technician requirements. (CCR 1793.7)

☐☐☐ The ratio is no less than one pharmacist to two technicians. (B&PC 4115[g], CCR 1793.7)

CORRECTIVE ACTION OR ACTION PLAN: _____

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9. Duties of Non-Licensed Personnel

Yes No N/A

☐☐☐ A non-licensed person (clerk/typist) is permitted to type a prescription label or otherwise enter prescription information into a computer record system, and at the direction of a pharmacist, may request and receive refill authorization. (B&P 4007,CCR 1793.3)

☐☐☐ The number of non-licensed personnel supervised by each pharmacist does not interfere with the effective performance of the pharmacist's responsibilities under the Pharmacy Law. (CCR 1793.3[b])

CORRECTIVE ACTION OR ACTION PLAN: _____

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PHARMACY PRACTICE

10. Pharmaceutical Service Requirements

The pharmacy complies with the requirements of 22 CCR 70263, addressing the following areas in written policies and procedures:

Yes No N/A

☐☐☐ Basic information concerning investigational drugs and adverse drug reactions;

☐☐☐ Repackaging and compounding records;

☐☐☐ Physician orders;

☐☐☐ Wards, nursing stations and night stock medications;

☐☐☐ Drugs brought into the facility by patients for storage or use;

☐☐☐ Bedside medications;

Yes No N/A

☐☐☐ Emergency drug supply;

☐☐☐ Pass medications;

☐☐☐ Inspection of ward stock, nursing stations and night lockers no less frequently than every 30-days\\Outdated drugs;

☐☐☐ Routine distribution of inpatient medications;

☐☐☐ Preparation, labeling and distribution of IV admixtures and cytotoxic agents;

☐☐☐ Handling of medication when pharmacist not on duty; and

☐☐☐ Use of electronic image and data order transmissions.

The pharmacy complies with the requirements of 22 CCR 70263, addressing the following areas:

☐☐☐ Destruction of controlled substances; and

☐☐☐ Development and maintenance of the hospital's formulary. (22 CCR 70263, CCR 1751, 1751.8)

CORRECTIVE ACTION OR ACTION PLAN: _____

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11. Medication/Chart Order

Yes No N/A

☐☐☐ The pharmacy receives the original, the electronic transmission, or a copy of the medication order. Faxed copies, tele-autograph copies, or transmissions between computers are permissible. (B&PC 4019, 4040, CCR 1717.4)

☐☐☐ The chart or medical record of the patient contains all of the information required by B&PC 4040 and the chart order is signed by the practitioner authorized by law to prescribe drugs if present or, if not present, within a specified time frame not exceeding 48 hours. (B&PC 4040, 22 CCR 70263[g])

☐☐☐ A copy of the chart order is maintained on the premises for three years. (B&PC 4081, 4105, 4333)

CORRECTIVE ACTION OR ACTION PLAN: _____

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12. Labeling and Distribution

Yes No N/A

☐☐☐ Unit dose medication and parenteral admixtures are properly labeled and include the information as required by B&PC 4076, or the information is otherwise readily available at the time of drug administration.(B&PC 4046)

Yes No N/A

☐☐☐ The pharmacist is responsible for the proper labeling, storage and distribution of investigational drugs pursuant to the written order of the investigator. (22 CCR 70263[o]).

☐☐☐ This pharmacy furnishes dangerous drugs in compliance with B&PC 4126.5 only to a patient pursuant to a prescription, a wholesaler from whom the dangerous drugs were purchased, a manufacturer from whom the drugs were purchased, a licensed wholesaler acting as a reverse distributor, another pharmacy to alleviate a temporary shortage with a quantity sufficient to alleviate the temporary shortage, a health care provider authorized to received drugs, or to another pharmacy of common ownership,

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

13. Duration of Drug Therapy

Yes No N/A

☐☐☐ The hospital has policies limiting the duration of drug therapy in the absence of the prescriber's specific indication of duration of drug therapy or under other circumstances recommended by the pharmacy and therapeutics committee or its equivalent and approved by the executive committee of the medical staff. Limitations are established for classes of drugs and/or individual drug entities. (22 CCR 70263[j])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

14. Confidentiality of Chart Orders, Prescriptions and Patient Medical Information

Yes No N/A

☐☐☐ Patient information is maintained to safeguard confidentiality. (Civil Code 56 et seq.)

☐☐☐ Patient medical information, all prescriptions (chart orders, patient discharge and employee prescriptions) are confidential and are not disclosed unless authorized by law. (B&PC 4040, CCR 1764)

☐☐☐ Destruction or disposal of patient records preserves the confidentiality of the information contained therein. (Civil Code 56.101)

☐☐☐ The pharmacy ensures electronically transmitted prescriptions (chart orders, discharge patient or employee prescriptions) are received, maintained and transmitted in a secure and confidential manner. (CCR 1717.4)

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

15. Quality Assurance and Medication Errors

Yes No N/A

☐☐☐ Pharmacy has established quality assurance program that documents medication errors attributable, in whole or in part, to the pharmacy or its personnel. (B&PC 4125, CCR 1711)

☐☐☐ Pharmacy quality assurance policies and procedures are maintained in the pharmacy and are immediately retrievable. (CCR 1711[c])

☐☐☐ When a medication error has occurred (drug was administered to or by the patient, or resulted in a clinically significant delay in therapy) the pharmacist communicates with the patient or patient's agent that a medication error has occurred and the steps required to avoid injury or mitigate the error. (CCR 1711[c][2][A], 1711[c][3])

☐☐☐ When a medication error has occurred (drug was administered to or by the patient, or resulted in a clinically significant delay in therapy) the pharmacist communicates to the prescriber that a medication error has occurred. (CCR 1711[c][2][B], 1711[c][3])

☐☐☐ Investigation of pharmacy medication errors is initiated within two business days from the date the medication error is discovered. (CCR 1711[d])

The record for quality assurance review for a medication error contains: (CCR 1711[e])

☐☐☐ Date, location, and participants in the quality assurance review;

☐☐☐ Pertinent data and other information related to the medication error(s) reviewed;

☐☐☐ Findings and determinations;

☐☐☐ Recommended changes to pharmacy policy, procedure, systems or processes, if any.

☐☐☐ The record of the quality assurance review is immediately retrievable in the pharmacy and is maintained in the pharmacy for at least one year from the date it was created. (CCR 1711[f])

☐☐☐ Pharmacists are not deviating from the requirements of a prescription except upon the prior consent of the prescriber, and selection of the drug product is in accordance with B&PC 4073 (generic substitution). (CCR 1716)

CORRECTIVE ACTION OR ACTION PLAN: _____

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16. Record Keeping Requirements

Yes No N/A

☐☐☐ A completed biennial pharmacy self -assessment is on file in the pharmacy and maintained for three years. (CCR 1715)

☐☐☐ All drug acquisition and disposition records (complete accountability) are maintained for at least three years. These records include:

Yes	No	N/A	
☐	☐	☐	Prescription records (CCR 4081[a])
☐	☐	☐	Purchase Invoices for all prescription drugs (4081[b])
☐	☐	☐	Biennial controlled substances inventory (21 CFR 1304.11)
☐	☐	☐	U.S. Official Order Forms (DEA Form-222) (21 CFR 1305.13)
☐	☐	☐	Power of Attorney for completion of DEA 222 forms (21 CFR 1305.07)
☐	☐	☐	Theft and Loss Reports (DEA Form 106) (21 CFR 1301.74[c])
☐	☐	☐	Record documenting return of drugs to wholesaler or manufacturer (CCR 4081)
☐	☐	☐	Record documenting transfers or sales to other pharmacies and prescribers (B&PC 4059, 4081, 4105, 4332, CCR 1718)
☐	☐	☐	Transfers or sales to other pharmacies and prescribers do not exceed five percent of the pharmacy's total annual purchases of dangerous drugs or devices. If more than five percent, registration with the board as a wholesaler has been obtained. (21CFR 1307.11, Prescription Drug Marketing Act [PDMA] [Pub. L. 100-293, Apr. 22, 1988] 503, B&PC 4160)
☐	☐	☐	If sales or distributions of controlled substances to other hospitals, pharmacies, or prescribers exceed five percent of the total number of controlled substances dosage units (that are furnished to the inpatients or dispensed on prescriptions to discharge patients or employees) per calendar year, the following have been obtained: a separate DEA distributor registration and a wholesaler's permit from the board. (21 CFR 1307.11, PDMA 503, B&PC 4160)
☐	☐	☐	A controlled substances inventory is completed biennially (every two years). Date completed: _____ (21 CFR 1304.13)
☐	☐	☐	Separate Schedule II records are maintained. This includes triplicate prescriptions, invoices, US official order forms and inventory records. (21 CFR 1304.04)
☐	☐	☐	Inventories and records for Schedule III-V controlled substances are filed separately or maintained in a readily retrievable manner that distinguishes them from other ordinary business records. (21 CFR 1304.04)
☐	☐	☐	DEA Forms-222 are properly executed. (21 CFR 1305.09)
☐	☐	☐	When the pharmacy distributes Schedule II controlled substances to other DEA registrants, Copy 2 of the DEA Form-222, properly completed, are submitted at the end of each month to the DEA Regional Office. (21 CFR 1309.09)
☐	☐	☐	Any controlled substances drug loss is reported upon discovery to the DEA and to the Board of Pharmacy within 30 days. (21 CFR 1301.74[c], CCR 1715.6)

Yes No N/A

☐☐☐ Records stored off-site (only for pharmacies who have obtained a waiver from the Board of Pharmacy to store records off-site) are secure and retrievable within two business days. Records for non-controlled substances are maintained on the licensed premises for at least one year from the date of dispensing. Controlled substances are maintained on the licensed premises for at least two years from the date of dispensing (CCR 1707)

☐☐☐ Do pharmacy staff hand initial prescription records and prescription labels, OR

☐☐☐ Does the pharmacy comply with the requirement for a pharmacist to initial or sign a prescription record or prescription label by recording the identity of the reviewing pharmacist in a computer system by a secure means. This computer does not permit the record to be altered after made and the record of the pharmacist's identity made in the computer system is immediately retrievable in the pharmacy. (CCR1712)

CORRECTIVE ACTION OR ACTION PLAN: _____

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17. After-Hours Supply of Medication

Yes No N/A

☐☐☐ The pharmacy maintains a record of the drugs taken from the after-hours supply of medications and the pharmacist is notified of such use. The record includes the name and strength of the drug, the amount taken, the date and time, the name of the patient to whom the drug was administered and the signature of the registered nurse. (22 CCR 70263[n])

CORRECTIVE ACTION OR ACTION PLAN: _____

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18. Drug Supplies for Use in Medical Emergencies

Yes No N/A

☐☐☐ A supply of drugs for use in medical emergencies only is immediately available at each nursing unit or service area as required. (22 CCR 70263[f])

☐☐☐ Written policies and procedures have been developed that establish the contents of the supply, procedures for use, restocking and sealing of the emergency drug supply. (22 CCR 70263[f][1])

☐☐☐ The emergency drug supply is stored in a clearly marked portable container which is sealed by the pharmacist in such a manner that a seal must be broken to gain access to the drugs. The contents of the container are listed on the outside cover and include the earliest expiration date of any drugs within. (Title 22 CCR 70263[f][2])

☐☐☐ The pharmacist is responsible for inspection of the drug supply at periodic intervals (no less frequently than every 30 days) specified in the writ ten policies. Records of the inspection are kept for at least three years. (22 CCR 70263[f][3])

CORRECTIVE ACTION OR ACTION PLAN: _____

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19. Schedule II-V Controlled Substances Floor Stock Distribution Records

Yes No N/A

☐☐☐ Records for the distribution of Schedule II-V controlled substances floor stock are open to inspection by authorized officers of the law and are preserved for at least three years from the date of making. (B&PC 4081)

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

20. Emergency Room Dispensing

A prescriber may dispense a dangerous drug, including a controlled substance, to an emergency room patient if all of the following apply (B&PC 4068[a]):

Yes No N/A

☐☐☐ The hospital pharmacy is closed and there is no pharmacist available in the hospital;

☐☐☐ The dangerous drug is acquired by the hospital pharmacy;

☐☐☐ The dispensing information is recorded and provided to the pharmacy when the pharmacy reopens;

☐☐☐ The hospital pharmacy retains the dispensing information and, if the drug is a schedule II or schedule III controlled substance, reports the dispensing information to the Department of Justice pursuant to Section 11165 of the Health and Safety Code;

☐☐☐ The prescriber determines that it is in the best interest of the patient that a particular drug regimen be immediately commenced or continued, and the prescriber reasonably believes that a pharmacy located outside the hospital is not available and accessible at the time of dispensing to the patient; and

☐☐☐ The quantity of drugs dispensed to any patient pursuant to this section are limited to that amount necessary to maintain uninterrupted therapy during the period when pharmacy services outside the hospital are not readily available or accessible, but shall not exceed a 72-hour supply;

☐☐☐ The prescriber shall ensure that the label on the drug contains all the information required by Section 4076. (B&PC 4068[a][7])

☐☐☐ The prescriber shall be responsible for any error or omission related to the drugs dispensed. (B&PC 4068[b])

☐☐☐ The brand name or generic name and manufacturer of the prescription drug is accurately identified on the label an prescription record. (B&PC 4076, CCR 1717)

☐☐☐ Controlled substances are dispensed in prescription containers bearing a federal warning label prohibiting transfer of the drugs. (CFR 290.5)

Yes No N/A

☐☐☐ Prescriptions are dispensed in new, senior-adult ease –of-opening tested, and child-resistant containers or in a noncomplying package, only pursuant to the prescription or when requested by the purchaser. (15 USC 1473 section 4[b], 16 CFR 1700.15. CCR 1717)

☐☐☐ Patient package inserts are dispensed with all estrogen and progesterone medications (21 CFR 310.515, 310.516)

CORRECTIVE ACTION OR ACTION PLAN: _____

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21. Discharge Medication/Consultation Services

Yes No N/A

☐☐☐ Patients receive information regarding each medication given at the time of discharge. The information includes the use and storage of each medication, the precautions and relevant warnings and the importance of compliance with directions. A written policy has been developed in collaboration with a physician and surgeon, a pharmacist, and a registered nurse and approved by the medical staff that ensures that each patient receives the medication consultation. (B&PC 4074, CCR 1707.2)

☐☐☐ Prescriptions are transmitted to another pharmacy as required by law. (B&PC 4072, CCR 1717[f], 1717.4)

☐☐☐ The prescription label contains all the required information. (B&PC 4076)

☐☐☐ Appropriate drug warnings are provided orally or in writing. (B&PC 4074, CCR 1744)

☐☐☐ The trade name or generic name and manufacturer of the prescription drug is accurately identified on the label and prescription record. (B&PC 4076, CCR 1717)

☐☐☐ Generic substitution for discharge medications is communicated to the patient, and the name of the dispensed drug product is indicated on the prescription label. (B&PC 4073)

☐☐☐ If the prescription is filled by a pharmacy technician, the pharmacist's initials are on the prescription label to document the pharmacist's verification of the product. (B&PC 4115[f], CCR 1793.7)

☐☐☐ Controlled substances are dispensed in prescription containers bearing a federal warning label prohibiting transfer of the drugs. (21 CFR 290.5)

☐☐☐ Prescriptions are dispensed in a new and child-resistant container, or senior-adult ease-of-opening tested container, or in a non-complying package only pursuant to the prescriber or when requested by the purchaser. (25 USC 1473 section 4[b], 16 CFR 1700.15, CCR 1717)

☐☐☐ Patient package inserts are dispensed with all estrogen and progesterone medications. (21 CFR 310.515, 310.516)

CORRECTIVE ACTION OR ACTION PLAN: _____

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22. Central Fill

Yes No N/A

☐☐☐ Pharmacy processes orders for the filling of patient cassettes for another hospital or Pharmacy receives filled medication orders or patient cassettes from another hospital. (CCR 1710[b])

- If the answer is yes, name of hospital: _____

☐☐☐ Pharmacy receives filled medication containers or cassettes from another pharmacy. (CCR 1710[b])

- If the answer is "yes", name of supplying pharmacy: _____
- If the answer to this and the previous question is "no" or "not applicable" go to Section 23.

☐☐☐ Prescription information is electronically transferred between the two pharmacies (CCR 1710[b][6])

☐☐☐ Pharmacy has a contract with the ordering hospital pharmacy or has the same owner. (CCR 1710[b][1])

☐☐☐ Filled cassettes are delivered directly to the ordering hospital pharmacy. (CCR 1710[b][2])

☐☐☐ Each cassette or container meets the requirements of Business and Professions Code section 4076 (CCR 1710[b][3]

☐☐☐ Complete and accurate records are maintained of each cassette fill transaction, including the name of the pharmacist checking the cassettes at each pharmacy. (CCR 1710[b][5])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

23. Policies and Procedures

There are written policies and procedures in place for:

Yes No N/A

☐☐☐ The assurance that each patient received information regarding each medication given at the time of discharge.

☐☐☐ Action to be taken to protect the public when a licensed individual employed by or with the pharmacy is known to be chemically, mentally, or physically impaired to the extent that it effects his or her ability to practice the profession or occupation authorized by his or her license; (B&PC 4104[a])

☐☐☐ Action to be taken to protect the public when a licensed individual employed by or with the pharmacy is known to have engaged in the theft or diversion or self-use of prescription drugs belonging to the pharmacy; (B&PC 4104[b])

Yes No N/A

☐☐☐ Oral consultation for discharge medications to an inpatient of a health care facility licensed pursuant to H&SC 1250, or to an inmate of an adult correctional facility or juvenile detention facility (B&PC 4074, CCR 1707.2[b][3]); and

☐☐☐ Operation of the pharmacy during the temporary absence of the pharmacist for breaks and meal periods including authorized duties of personnel, pharmacist's responsibilities for checking all work performed by ancillary staff, and pharmacist's responsibility for maintaining the security of the pharmacy. (CCR 1714.1[f])

☐☐☐ Assuring confidentiality of medical information if your pharmacy maintains the required dispensing information for prescriptions, other than controlled substances, in a shared common electronic file. (CCR1717.1[e])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

24. Compounding Sterile Injectable Drugs

a. Compounding Area for Parenteral Solutions (if applicable)

Yes No N/A

☐☐☐ Pharmacy has a board issued Licensed Sterile Compounding permit or has current accreditation from the Joint Commission on Accreditation of Healthcare Organizations, or other board approved accreditation agency. (B&PC 4127.1(a) and 4127.1[d])

LSC Permit # _____ or

Name of accreditation agency _____

The pharmacy has a designated area or cleanroom for the preparation of sterile products that has the following:

☐☐☐ An ISO class 5 laminar airflow hood within an ISO class 7 cleanroom (B&PC 4127.7[a]);

☐☐☐ A positive air pressure differential in the cleanroom that is relative to adjacent areas (B&PC 4127.7[a]);

☐☐☐ An ISO class 5 cleanroom ((B&PC 4127.7[b]);

☐☐☐ A barrier isolator that provides an ISO class 5 environment for compounding ((B&PC 4127.7[c]); and

☐☐☐ The preparation of sterile injectable products is conducted in an environment that meets criteria specified in pharmacy's written policies and procedures. (CCR 1751.01[a])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

b. Facility and Equipment Standards

Yes No N/A

☐☐☐ The compounding environment meets criteria specified in pharmacy's written policies and procedures for safe compounding of sterile injectable drugs. (CCR 1751.01[a])

☐☐☐ Only those who are properly attired (pursuant to ((CCR 1751.4) are allowed in the cleanroom. ((CCR 1751.01[b])

☐☐☐ All equipment used in the designated cleanroom is made of easily cleaned and disinfected material. (CCR 1751[c])

☐☐☐ Exterior workbench surfaces and other hard surfaces in the cleanroom, such as walls, floors, ceilings, shelves, tables, and stools are disinfected weekly and after any unanticipated event that could increase risk of contamination. (B&PC 1751.01[d])

☐☐☐ There are current and appropriate reference materials regarding the compounding of sterile injectable products located in or immediately available to the pharmacy. (CCR 1751.9)

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

c. Policies and Procedures

The pharmacy has written policies and procedures associated with the preparation and dispensing of sterile injectable products and includes: (CCR 1751.02)

Yes No N/A

☐☐☐ Compounding, filling, and labeling of sterile injectable compounds;

☐☐☐ Labeling of the sterile injectable product based on the intended route of administration and recommended rate of administration;

☐☐☐ Equipment and supplies;

☐☐☐ Training of staff in preparation of sterile injectable products;

☐☐☐ Training of patient and/or caregiver in the administration of compounded sterile injectable products;

☐☐☐ Procedures for the handling and disposal of cytotoxic agents;

☐☐☐ Quality assurance program; and

☐☐☐ Record keeping requirements.

☐☐☐ Ingredients and compounding process for each preparation is determined in writing and reviewed by a pharmacist before compounding begins. ((CCR 1751.02 [b])

If compounding sterile injectable products from one or more non-sterile ingredients, the pharmacy has written policies and procedures that comply with the following:

Yes No N/A

☐☐☐ Policies and procedures are immediately available to all compounding personnel and board inspectors (CCR 1751.02 [c][1]); and

☐☐☐ All compounding personnel have read the policies and procedures, any additions, revisions, and deletions before compounding. (CCR 1751.02 [c][2])

Policies and procedures address the following: (CCR 1751.02 [c][3] [A-K])

☐☐☐ Competency evaluation;

☐☐☐ Storage and handling of products and supplies;

☐☐☐ Storage and delivery of final products;

☐☐☐ Process validation;

☐☐☐ Personnel access and movement of materials into and near the controlled area;

☐☐☐ Use and maintenance of environmental control devices used to create the critical area for manipulation of sterile products (i.e., laminar-airflow workstations, biological safety cabinets, class 100 cleanrooms, and barrier isolator workstations;

☐☐☐ A regular cleaning schedule for the controlled area and any equipment in the controlled area and the alternation of disinfectants. Pharmacies subject to an institutional infection control policy may follow that policy as it relates to cleaning schedules;

☐☐☐ Disposal of packaging materials, used syringes, containers, and needles to enhance sanitation and avoid accumulation in the controlled area;

☐☐☐ For sterile batch compounding, written policies and procedures for the use of master formulas and work sheets and for appropriate documentation;

☐☐☐ Sterilization; and

☐☐☐ End-product evaluation and testing.

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

d. Labeling

The pharmacy's compounded sterile injectable product labels contain: (CCR 1751.2)

☐☐☐ Telephone number of the pharmacy, unless dispensed for a hospital in-patient;

Yes No N/A

☐☐☐ Name and concentrations of ingredients contained in the product;

☐☐☐ Instructions for storage and handling; and

☐☐☐ A special label which states "Chemotherapy—Dispose of Properly" for all cytotoxic agents.

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

e. Record keeping Requirements

Yes No N/A

☐☐☐ Pharmacy records for sterile injectable products produced for future use (pursuant to section 1716.1), in addition to record requirements of section 1716.2, contain the name, lot number, amount, and date on which the products were provided to a prescriber. (CCR 1751.3[a])

☐☐☐ Records for sterile products compounded from one or more non-sterile ingredients are maintained for at least three years and contain the following: (CCR 1751.3[b])

☐☐☐ The training and competency evaluation of employees in sterile product procedures;

☐☐☐ Refrigerator and freezer temperatures;

☐☐☐ Certification of the sterile compounding environment;

☐☐☐ Other facility quality control logs specific to the pharmacy's policies and procedures (e.g., cleaning logs for facilities and equipment);

☐☐☐ Inspection for expired or recalled pharmaceutical products or raw ingredients; and

☐☐☐ Preparation records including the master work sheet, the preparation work sheet, and records of end-product evaluation results.

☐☐☐ The pharmacy maintains records of validation processes as required by Section 1751.7(b) for three years. (CCR 1751.3[c])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

f. Attire

Yes No N/A

☐☐☐ When preparing cytotoxic agents, gowns and gloves are worn. (CCR 1751.4[a])

When compounding sterile products from one or more non-sterile ingredients and a barrier isolator is <u>not</u> used:

Yes No N/A

☐☐☐ Cleanroom garb is donned and removed outside the designated area; (CCR 1751.4[b][2])

☐☐☐ Individuals in the cleanroom wear a low-shedding coverall, head cover, face mask, and shoe covers; (CCR 1751.4[b][1])

☐☐☐ No hand, finger, or wrist jewelry is worn or if the jewelry cannot be removed, it is cleaned and covered with a sterile glove; (CCR 1751.4[b][3])

☐☐☐ Head and facial hair is kept out of critical area or covered (CCR 1751.4[b][4]); and

☐☐☐ Gloves of low-shedding material are worn. (CCR 1751.4[b][5])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

g. Training of Staff, Patient, and Caregiver

Yes No N/A

☐☐☐ Consultation is available to the patient and/or primary caregiver concerning proper use of sterile injectable products and related supplies furnished by the pharmacy. (CCR 1751.5[a])

☐☐☐ The pharmacist-in-charge ensures that all pharmacy personnel engaging in compounding sterile injectable drug products has training and demonstrated competence in the safe handling of those products, including cytotoxic agents if the pharmacy compounds such agents. (CCR 1751.5[b])

☐☐☐ Records of training and demonstrated competence are available for each individual and are retained for three years beyond the employment period. (CCR 1751.5[c])

☐☐☐ The pharmacist-in-charge ensures the continuing competence of pharmacy personnel engaged in compounding sterile injectable products. (CCR 1751.5[d])

☐☐☐ When compounding sterile products from one or more non-sterile ingredients, the pharmacy complies with the following training requirements: (CCR 1751.5[e])

☐☐☐ The pharmacy follows a written program of training and performance evaluation designed to ensure that each person working in the designated area has the knowledge and skills necessary to perform their assigned tasks properly. This program of training and performance evaluation addresses the following: (CCR 1751.5[e][1][A-J])

☐☐☐ Aseptic technique;

☐☐☐ Pharmaceutical calculations and terminology;

☐☐☐ Sterile product compounding documentation;

☐☐☐ Quality assurance procedures;

Yes No N/A

☐☐☐ Proper gowning and gloving technique;

☐☐☐ General conduct in the controlled area;

☐☐☐ Cleaning, sanitizing, and maintaining equipment used in the controlled area;

☐☐☐ Sterilization techniques; and

☐☐☐ Container, equipment, and closure system selection.

☐☐☐ Each person assigned to the controlled area successfully completes practical skills training in aseptic technique and aseptic area practices. (CCR 1751.5[e][2])

☐☐☐ Evaluation includes written testing and a written protocol of periodic routine performance checks involving adherence to aseptic area policies and procedures.

☐☐☐ Each person's proficiency and continuing training is reassessed every 12 months.

☐☐☐ Results of these assessments are documented and retained in the pharmacy for three years.

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

h. Disposal of Waste Material

Yes No N/A

☐☐☐ The pharmacy has written policies and procedures for the disposal of infectious material and/or materials containing cytotoxic residues. (CCR 1751.6)

☐☐☐ The procedures include the cleanup of spills and are in conformance with local health jurisdiction. (CCR 1751.6)

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

i. Quality Assurance and Process Validation

Yes No N/A

☐☐☐ There is a documented, ongoing quality assurance program that monitors personnel performance, equipment, and facilities, and the pharmacist-in-charge assures that the end product meets the required specifications by periodic sampling. (CCR 1751.7[a])

The Quality Assurance Program contains at least the following: (CCR 1751.7[a][1-5])

☐☐☐ Cleaning and sanitization of the parenteral medication preparation area;

Yes No N/A

☐☐☐ Batch produced sterile injectable drug products compounded from one or more non-sterile ingredients are subject to documented end product testing for sterility and pyrogens and are quarantined until the end product testing confirms sterility and acceptable levels of pyrogens;

☐☐☐ The storage of compounded sterile injectable products in the pharmacy and periodic documentation of refrigerator temperature;

☐☐☐ Steps to be taken in the event of a drug recall; and

☐☐☐ Written justification of the chosen expiration dates for compounded sterile injectable products in accordance with CCR 1716.2[a][3])

☐☐☐ Each individual involved in the preparation of sterile injectable products successfully completes a validation process on technique before being allowed to prepare sterile injectable products. (CCR 1751.7[b])

☐☐☐ The validation process is carried out in the same manner as normal production, except that an appropriate microbiological growth medium is used in place of the actual product used during sterile preparation. (CCR 1751.7[b])

☐☐☐ The validation process is representative of all types of manipulations, products and batch sizes the individual is expected to prepare. (CCR 1751.7[b])

☐☐☐ The same personnel, procedures, equipment, and materials are involved. (CCR 1751.7[b])

☐☐☐ Completed medium samples are incubated. (CCR 1751.7[b])

☐☐☐ If microbiological growth is detected, the sterile preparation process is evaluated, corrective action taken, and the validation process is repeated. (CCR 1751.7[b])

☐☐☐ Personnel competency is revalidated and documented at least every 12 months, whenever the quality assurance program yields an unacceptable result, when the compounding process changes, equipment used in the compounding of sterile injectable drug products is repaired or replaced, the facility is modified in a manner that affects airflow or traffic patterns, or whatever aseptic techniques are observed. (CCR 1751.7[b])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

j. Reference Materials

Yes No N/A

☐☐☐ Current reference materials are maintained or available to the pharmacy on the drugs and chemicals used in parenteral therapy services and all parenteral therapy manufacturing, dispensing, distribution, and counseling services provided. (CCR 1751.9)

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

PHARMACIST-IN-CHARGE CERTIFICATION:

I, (please print) _____, RPH # _____ hereby certify that I have completed the self-assessment of this pharmacy of which I am the pharmacist-in-charge. I understand that all responses are subject to verification by the Board of Pharmacy. I further state under penalty of perjury that the information contained in this self-assessment form is true and correct.

Signature _____ Date _____
(Pharmacist-in-Charge)

Legal References used in the self-assessment forms (California Code of Regulations [CCR], Title 16 and Title 24, and Business and Professions Code [B&PC], Chapter 9, Division 2) can be found in the *California Pharmacy Law* (below) or visit the Board of Pharmacy Web site at www.pharmacy.ca.gov under *California Pharmacy Law and Index.*

The Health and Safety Code (H&SC), Division 10, Uniform Controlled Substances Act is also in the *California Pharmacy Law* (below) or you can visit the Board of Pharmacy Web site at www.pharmacy.ca.gov under *California Pharmacy Law and Index.*

California Code of Regulations (CCR), Chapter 1, Division 5, Title 22, and other references can be found in the California State Law Library or county law libraries.

Code of Federal Regulations (CFR), Title 21, Chapter II, Drug Enforcement Administration, may be found at www.dea.gov.

California Board of Pharmacy
400 R Street, Suite 4070
Sacramento CA 95814
(916) 445-5014
fax: (916) 327-6308
www.pharmacy.ca.gov

California Pharmacy Law may be obtained by contacting:
Law Tech
1060 Calle Cordillera, Suite 105
San Clements CA 92673
(800) 498-0911 Ext. 74
www.lawtech-pub.com

Pharmacist Recovery Program
(800) 522-9198 (24 hours a day)

Atlantic Associates, Inc. (CURES)
Prescription Collection
8030 S. Willow Street, Bldg. III, Unit 3
Manchester NH 03103
(888) 492-7341

Medical Board of California
1426 Howe Avenue, Suite 54
Sacramento CA 95825
(800) 633-2322
(916) 263-2499
fax: (916) 263-2387
www.medbd.ca.gov

The **Drug Enforcement Administration** may be contacted at:

DEA - Los Angeles
255 East Temple Street, 20th Floor
Los Angeles CA 90012
(213) 894-2216, 2217, 4697, or 6711
(213) 894-4016 (Diversion or Investigation)

DEA – San Francisco
450 Golden Gate Avenue
San Francisco CA 94102
(415) 436-7900
(415) 436-7854 (Theft Reports or Diversion)

DEA - Sacramento
1860 Howe Avenue
Sacramento CA 95825
(916) 566-7160

DEA - Riverside
4470 Olivewood Avenue
Riverside, CA 92501-6210
(909) 328-6200

DEA - Fresno
2444 Main Street, Suite 240
Fresno, CA 93721
(559) 487-5402

DEA – San Diego
4560 Viewridge Avenue
San Diego, CA 92123-1637
(858) 616-4100

DEA – Oakland
1301 Clay Street, Suite 460N
Oakland, CA 94612
(510) 637-5600

DEA – San Jose
One North First Street, Suite 405
San Jose, CA 95113
(408) 291-7235

ATTACHMENT G

Longs Drug Stores

General Offices: 141 North Civic Drive, P.O. Box 5222, Walnut Creek, California 94596, (925) 937-1170

August 27, 2004

Patricia Harris, Executive Officer
California State Board of Pharmacy
400 R Street, Suite 4070
Sacramento, CA 95814

RE: REQUEST FOR WAIVER—CCR 1717(e)

Dear Ms. Harris:

I want to thank you for speaking with Mr. Cantrell and I today regarding the July 19, 2004 letter that Chris Gong, on behalf of Longs Drug Stores, submitted to the Board. In that letter, Longs Drug Stores expressed interest in being able to install convenient, yet secure and private, 24-Hour Prescription Drop Kiosks. These kiosks would be installed adjacent to or in the parking lot at various Longs Drug Stores in California, for patients to use as an easy means to drop off those prescriptions they want the pharmacy to fill. Caution in reviewing all prescriptions placed in the kiosk, to determine the prescription's validity, authenticity, verify it has no uncertainties, etc. would be addressed in the same manner as prescriptions today, that are called, faxed, or brought directly into the pharmacy, are handled.

Since the California lifestyle is very diverse, yet also extremely time conscious, if a patient's access to a pharmacy service can be improved, that patient's drug therapy compliance level could also be expected to improve. Currently the California Code of Regulations, Section 1717(e) states in pertinent part that licensees may not participate in any arrangement that allows prescriptions to be accepted by or left at any place other than a licensed retail pharmacy. This same section though, also allows for the Board to waive this section for good cause.

As such, Longs Drug Stores is requesting a waiver for California Code of Regulations, Section 1717(e), so that it may install and utilize 24-Hour Prescription Drop Kiosks at many of its pharmacies throughout the state. In requesting this waiver, Longs asks that the matter be added to the agenda of the Board's next Enforcement meeting and also be placed on the full agenda for the Board's October Board meeting.

Should you have any questions, please do not hesitate to contact me.

Sincerely,

Orriette A. Quandt, PharmD
Corporate Pharmacy Compliance Manager,
Longs Drug Stores

Longs Drugs
Live healthy. Live happy. Live Longs.

CONCEPT 3-1

- Drop door (under logo header) displays information on drop box program
- Literature door (under drop door) contains large amount of take-home literature
- A chained pen can be attached onto surface of literature door
- Added “24-hour Dropoff” to logo area graphic
- Top graphic area back lit
- Height: 6 ft
- Width: 27 inches
- Depth: 18 inches

AGI Schutz MERCHANDISING

Longs Drugs
Live healthy. Live happy. Live Longs.

CONCEPT 3-1

Canopy Version

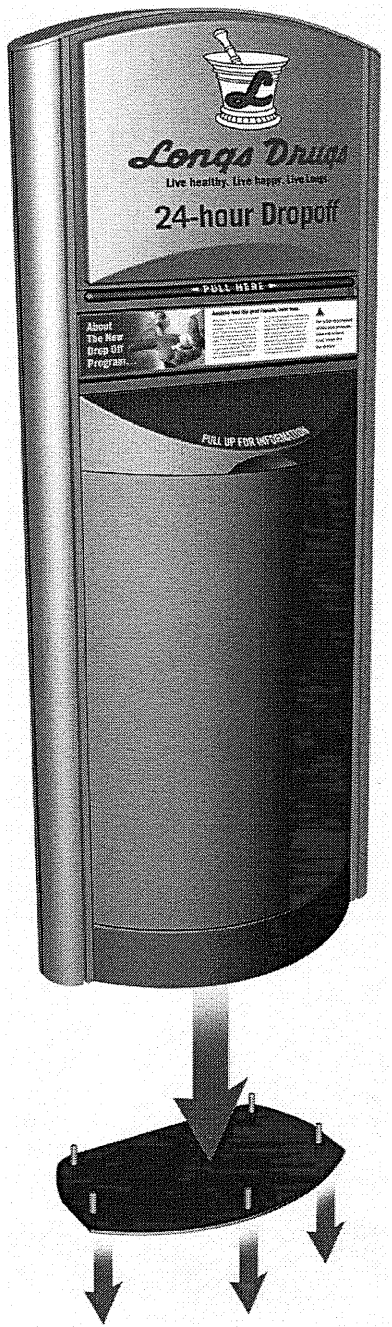
- Protective all-weather overhead canopy

AGI Schutz MERCHANDISING

Longs Drugs
Live healthy. Live happy. Live Longs.

CONCEPT 3-1

Attachment to ground



- Bottom plate is bolted to the concrete surface
- Unit is fastened to plate bolted from the inside of the drop box

AGI Schutz MERCHANDISING

Longs Drugs
Live healthy. Live happy. Live Longs.

CONCEPT 3-1

Retrieval Area Open

- Door is secured with lock and key
- Trash receptacle is part of the door to hold discarded forms

AGI Schutz MERCHANDISING

Longs Drugs
Live healthy. Live happy. Live Longs.

CONCEPT 3-1

Drop Bin Open

- As door opens, tray receives prescription materials
- Tray prohibits access to anything inside box
- Prescription materials are deposited as door is closed

AGI Schutz MERCHANDISING

"Lowell McNicol"
<Lowell_McNicol@msn.com>

09/29/2004 07:43 AM

Subject: Fw: Dental Hygienists

Dear Patti,

Please pass this article of mine, along to the Board members. It has bearing on **"kiosks"** and **"automated dispensing devices."**

Thanks,

Lowell McNicol
----- Original Message -----
From: Lowell McNicol
To: Lowell_McNicol@msn.com
Sent: Wednesday, September 29, 2004 12:22 AM
Subject: Fw: Dental Hygienists

----- Original Message -----
From: Lowell McNicol
To: Fred Mayer ; Allen Gordon ; Barry Solomon ; Bill Keane ; Burt Sukhov ; CEPA ; Howard Fong ; Jack Light ; Jerry Feitelberg ; Leslie McNicol ; maxileem ; Nick Wilson ; Phil Grauss ; Priscilla Gale ; Joe Rotenberg ; John Meyers
Sent: Wednesday, September 29, 2004 12:14 AM
Subject: Fw: Dental Hygienists

----- Original Message -----
From: Lowell McNicol
To: Lowell_McNicol@msn.com
Sent: Tuesday, September 28, 2004 11:58 PM
Subject: Dental Hygienists

Dental Hygienists

I found out yesterday (9-27-04) that the Dental Hygienist training curriculum at UCSF has been discontinued. This revelation floored me. It was a top notch program which has been in operation for at least the 42 years since I began my studies at UCSF School of Pharmacy. I was told by a dental hygienist alumnus of UCSF that it was done for economic reasons. It seems that nowadays, a certified dental hygienist can come right out of a two year junior college program. And

according to her, many dentists like the idea because they can charge the same amount for dental hygiene care in their offices while paying the less qualified "hygienist" less money. In other words, this dumbing-down of dental hygienists' care will translate into increased profits for the dental profession. The UCSF hygienists don't like it, but I guess there's not much to be done about it.

The dental hygienists' dilemma reminds me of the plight of pharmacists. Their acumen, their expertise, is being replaced by something cheaper. I read somewhere recently, that jobs that are at risk of being outsourced, or shipped offshore, generally have two things in common. They are jobs where the business at hand is primarily performed by telephone or via computer. The work of retail and hospital pharmacists meet both of these criteria. Our expertise, our acumen, is being inexorably replaced by cheaper, minimally trained employees, and by cheaper-to-operate kiosks and automated dispensing devices. Entire dispensing services are being outsourced to offsite warehouse dispensing operations. The ranks of existing pharmacists are being flooded by less expensive H1B visa-holding pharmacists from other countries. Indeed, a significant percentage of U.S. pharmacy business has effectively gone offshore. Pharmacies in Canada, Mexico and elsewhere are filling prescriptions for U.S. citizens much more cheaply than we can ourselves. In fact, the world wide web is responsible for much of this flight of prescriptions from domestic pharmacies. And not much can be done about the international internet business. There are token seizures here and there and the occasional arrest. But as long as we operate as a free society, the population is going to get what it perceives as its legitimately needed prescriptions, as cheaply and conveniently as possible. I think that pharmacists must face the fact that their jobs are currently being outsourced, and shipped offshore. Pharmacists and dental hygienists have been sold out.

Lowell McNicol Pharm.D.
855 Cherry St.
Petaluma, CA. 94952
707-762-8383
Sept. 28, 2004

ATTACHMENT H

Longs Drugs

General Offices: 141 North Civic Drive, P.O. Box 5222, Walnut Creek, California 94596, (925) 937-1170

SENT VIA E-MAIL AND U. S. MAIL

September 20, 2004

Patricia Harris, Executive Officer
California State Board of Pharmacy
400 R Street, Suite 4070
Sacramento, CA 95814

Re: REQUEST FOR WAIVER—CCR 1717(e)

Dear Ms. Harris:

Pursuant to our previous letters and recent communication, Longs Drug Stores would like to request a waiver to install and utilize self service dispensing units, such as the Asteres ScriptCenter, at various Longs Drug Stores in California.

The Asteres ScriptCenter Unit is an automated, self-contained instrument that allows patients to access their filled prescriptions. These units would be installed in close proximity to the pharmacy area. To improve patient convenience and therapeutic compliance, these units may be accessed by a patient during pharmacy hours or during those times when the main store is open, but the pharmacy is closed.

At the request of a patient and through the use of a secure method designed to guard against inappropriate access, a patient may retrieve his/her filled prescription from the unit at their convenience. New prescriptions, or those prescriptions requiring consultation, will not be available through these units.

Prescriptions would be filled by a pharmacist, using the same safeguards that are currently in place. These filled prescriptions would then be input into these units either by a pharmacist or a pharmacy staff member, under the supervision of a pharmacist. As medications are input into the units, security measures are used to ensure accurate dispensing.

Longs has also requested that the manufacturer of the Asteres Dispensing Unit provide the Board with additional information, specifically illustrating the unit's numerous privacy and security features.

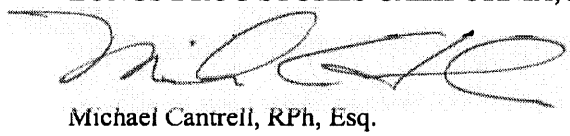
Since the California lifestyle is very diverse, Longs Drug Stores is seeking ways to improve a patient's access to pharmacy services, in hopes of improving the patient's compliance with their prescribed drug regimen. Currently the California Code of Regulations, Section 1717(e) places limitations as to how a patient may receive his/her prescription, but also allows the Board to waive this section for good cause.

As such, Longs Drug Stores is requesting a waiver for California Code of Regulations, Section 1717(e), so that it may install and utilize self service dispensing units at its pharmacies throughout the state. In requesting this waiver, Longs asks that the matter be added to the agenda of the Board's next Enforcement meeting and also be placed on the full agenda for the Board's October Board meeting.

Should you have any questions, please do not hesitate to contact me.

Sincerely,

LONGS DRUG STORES CALIFORNIA, INC.



Michael Cantrell, RPh, Esq.
Vice President Professional Services

MLC/me

cc: Cooky Quandt, R.Ph.

Introducing ScriptCenter™

ASTERES

The first self-service finished prescription pick-up machine

Bob Hansen, PharmD
Vice President, Pharmacy Services

What does ScriptCenter do?

- Automates the storage and purchase of finished prescriptions
- Allows customers to pick up and pay for finished prescriptions
- Provides access when store is open, pharmacy closed

ASTERES

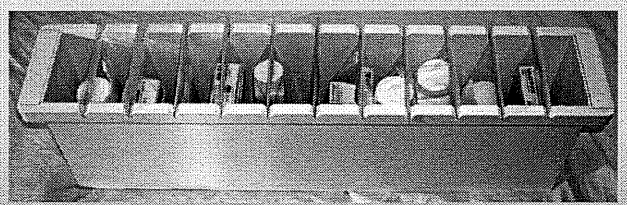
ScriptCenter in the store

ASTERES

How does ScriptCenter work?

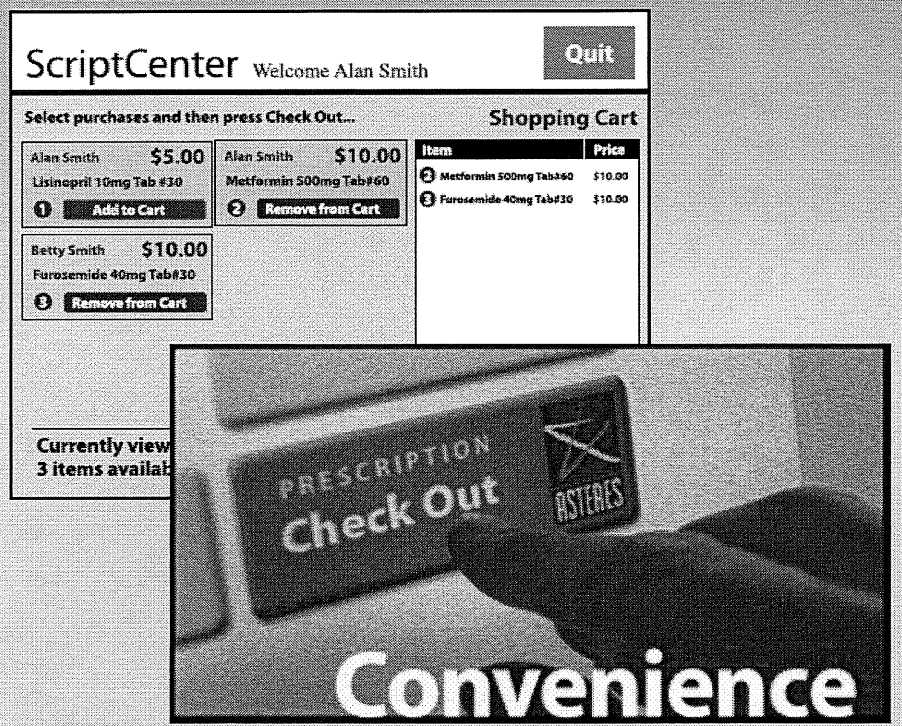
Fill → Load → Pay

- Fill prescriptions as usual
- Place prescriptions in bags
- Link bar-coded bags to prescriptions
- Load bags into trays
- Load trays into ScriptCenter
- Customers purchase from ScriptCenter



ASTERES

How do customers use ScriptCenter?



- Login
- Select prescriptions
- Sign and acknowledge
- Pay
- Remove from bin
- Take receipt

ASTERES

Security Features

- One prescription per bag
- Bar code assures patient/RX match
- Electronic signature and photo log
- Equipped with floor bolts & door locks
- Privacy screen for confidentiality

ASTERES

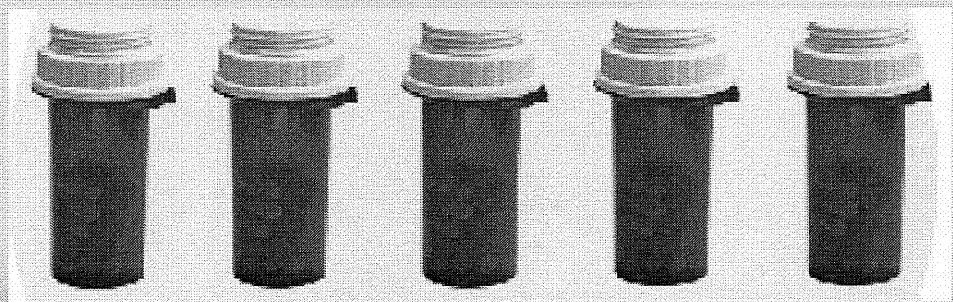
Who uses ScriptCenter?

- ScriptCenter is not for everybody
- ScriptCenter is for:
  - Patients who opt in
  - Refills
  - Patients on maintenance meds
    - OC, thyroid, antihistamines
  - Comfortable with ATMs
  - Busy lifestyle
  - Appreciate convenience

ASTERES

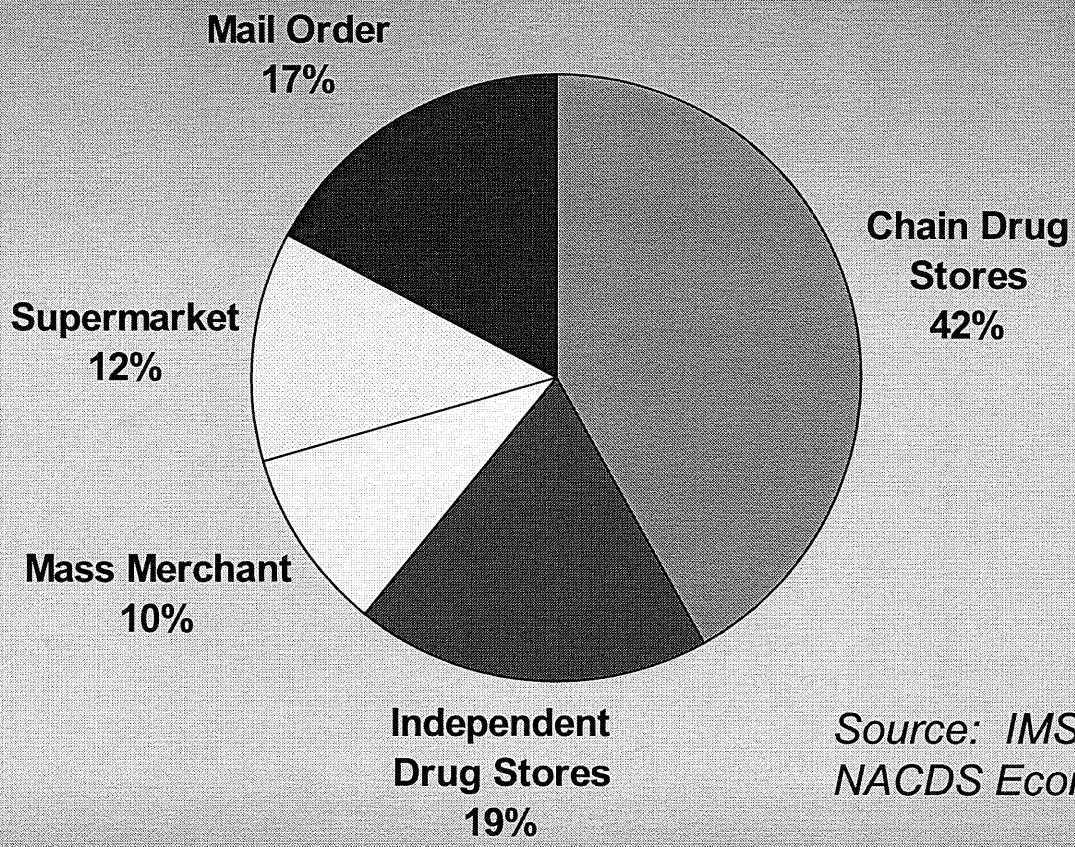
ScriptCenter Benefits

- Improves customer service
- Extends pharmacy hours for pick up
- Shifts work away from the register
- Provides merchandising opportunities
- **Keeps patients in the pharmacy**



ASTERES

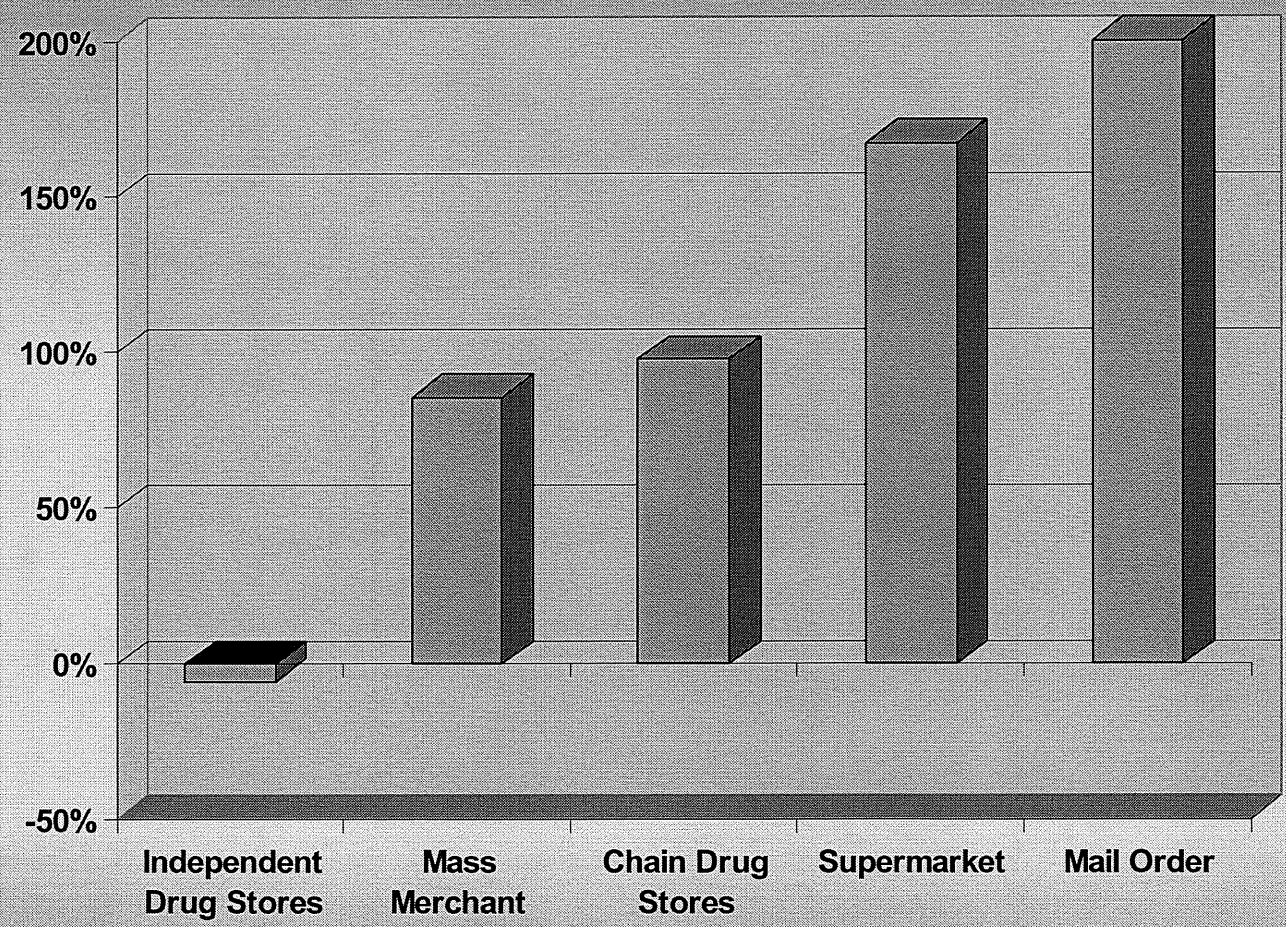
Prescription sales 2003



Source: IMS Health and NACDS Economics Department

ASTERES

Growth in business 1992 - 2003



ASTERES

Customer Satisfaction

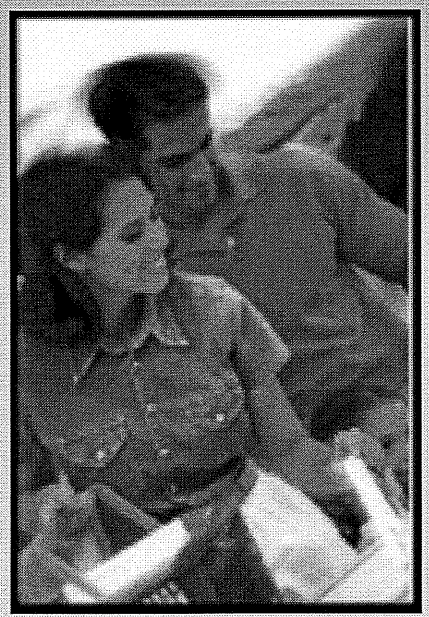
- Easy to use
- Shorter lines
- More control
- Greater privacy
- Added convenience

- **Provides additional choice**

ASTERES

The Shift to Self-Checkout

Banks → Airlines → Retail → Pharmacy



- 30% will use self-checkout if offered*
- 44% more likely to shop at a store offering self-checkout*
- 70% say they would be likely to try self-checkout*

***Source: NCR Fastlane**

ASTERES

Consumer Survey Results

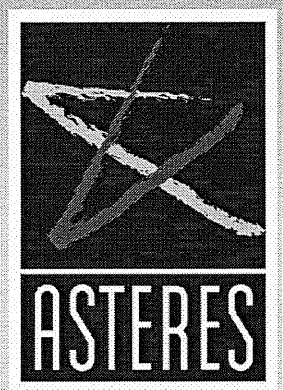
Nov. 4-21, 2003

Retail drug store - San Diego, CA

- 450 surveys collected
- 99% - easy to use
- 92% - likely to use
- 31% - requested email notification

ASTERES

Thank you!



www.Asteres.com

ATTACHMENT I

State of California Department of Consumer Affairs

Memorandum

To: Enforcement Committee Date: September 16, 2004

From: Paul Riches
Chief of Legislation and Regulation

Subject: Receipt and Delivery of Prescriptions

Requests have been made by Longs Drugs, Inc. to permit the use of secure drop boxes for receiving prescription orders from patients and to permit the use of secure devices for dispensing filled prescriptions after hours. Those requests are attached for your reference. Below is proposed regulation language to permit both these activities. The prescription drop boxes will allow patients to drop off prescriptions while the pharmacy is closed. The secure devices for dispensing prescriptions after hours is restricted to refill prescriptions that are not subject to the consultation requirement. The proposed draft relocates existing provisions in Section 1717(e) into a new section and provides the authorization for both the drop boxes and dispensing devices.

Add Section 1713

§1713 Receipt and Delivery of Prescriptions

(a) Except as otherwise provided in this Division, no licensee shall participate in any arrangement or agreement, whereby prescriptions, or prescription medications, may be left at, picked up from, accepted by, or delivered to any place not licensed as a retail pharmacy.[1]
(b) A licensee may pick up prescriptions at the office or home of the prescriber or pick up or deliver prescriptions or prescription medications at the office of or a residence designated by the patient or at the hospital, institution, medical office or clinic at which the patient receives health care services.[2]
(c) A patient or the patient's agent may deposit a prescription in a secure container that is at the same address or adjoining the licensed premises. The pharmacy shall be responsible for the security and confidentiality of the prescriptions deposited in the container.
(d) A pharmacy may use a device to dispense refilled prescriptions provided:
(1) The device is located at the same address or adjoining the licensed premises.
(2) The device has a means to identify the patient and only release that patient's prescriptions.
(3) The device is secure from access and removal by unauthorized individuals.
(4) The pharmacy provides a means for the patient to obtain a consultation with a pharmacist if requested by the patient.
(5) The pharmacy is responsible for the prescriptions stored in the device.
(e) A pharmacist shall not use a device to dispense a refilled prescription if the pharmacist determines that the patient requires counseling pursuant to Section 1707.2 (a) (2).

---

[1] Moved from 1717 (e).
[2] Moved from 1717 (e).

§1717. ~~Pharmaceutical~~ Pharmacy Practice.

(a) No medication shall be dispensed on prescription except in a new container which conforms with standards established in the official compendia.
Notwithstanding the above, a pharmacist may dispense and refill a prescription for non-liquid oral products in a clean multiple-drug patient medication package (patient med pak), provided:
(1) a patient med pak is reused only for the same patient;
(2) no more than a one-month supply is dispensed at one time; and
(3) each patient med pak bears an auxiliary label which reads, "store in a cool, dry place."
(b) In addition to the requirements of Business and Professions Code Section 4040 ~~4036, Business and Professions Code~~, the following information shall be maintained for each prescription on file and shall be readily retrievable:
(1) The date dispensed, and the name or initials of the dispensing pharmacist. All prescriptions filled or refilled by an intern pharmacist must also be initialed by the supervising pharmacist ~~preceptor~~ before they are dispensed.
(2) The brand name of the drug or device; or if a generic drug or device is dispensed, the distributor's name which appears on the commercial package label; and
(3) If a prescription for a drug or device is refilled, a record of each refill, quantity dispensed, if different, and the initials or name of the dispensing pharmacist.
(4) A new prescription must be created if there is a change in the drug, strength, prescriber or directions for use, unless a complete record of all such changes is otherwise maintained.
(c) Promptly upon receipt of an orally transmitted prescription, the pharmacist shall reduce it to writing, and initial it, and identify it as an orally transmitted prescription. If the prescription is then dispensed by another pharmacist, the dispensing pharmacist shall also initial the prescription to identify him or herself. All orally transmitted prescriptions shall be received and transcribed by a pharmacist prior to compounding, filling, dispensing, or furnishing.
Chart orders as defined in Section 4019 of the Business and Professions Code are not subject to the provisions of this subsection.
(d) A pharmacist may furnish a drug or device pursuant to a written or oral order from a prescriber licensed in a State other than California in accordance with Business and Professions Code Section 4005.
(e) ~~No licensee shall participate in any arrangement or agreement, whereby prescriptions, or prescription medications, may be left at, picked up from, accepted by, or delivered to any place not licensed as a retail pharmacy.~~
~~However, a licensee may pick up prescriptions at the office or home of the prescriber or pick up or deliver prescriptions or prescription medications at the office of or a residence designated by the patient or at the hospital, institution, medical office or clinic at which the patient receives health care services. The Board may in its sole discretion waive this application of the regulation for good cause shown.~~
~~(f)~~ A pharmacist may transfer a prescription for Schedule III, IV or V controlled substances to another pharmacy for refill purposes in accordance with Title 21, Code of Federal Regulations, 1306.26.
Prescriptions for other dangerous drugs which are not controlled substances may also be transferred by direct communication between pharmacists or by the receiving pharmacist's access to prescriptions or electronic files that have been created or verified by a pharmacist at the transferring pharmacy. The receiving pharmacist shall create a written prescription; identifying it as a transferred prescription; and record the date of transfer and the original prescription number. When a prescription transfer is accomplished via direct access by the receiving pharmacist, the receiving pharmacist shall notify the transferring pharmacy of the transfer. A pharmacist at the transferring pharmacy shall then assure that there is a record of the prescription as having been transferred, and the date of transfer. Each pharmacy shall maintain inventory accountability and

pharmacist accountability and dispense in accordance with the provisions of Section 1716. Information maintained by each pharmacy shall at least include:

(1) Identification of pharmacist(s) transferring information;

(2) Name and identification code or address of the pharmacy from which the prescription was received or to which the prescription was transferred, as appropriate;

(3) Original date and last dispensing date;

(4) Number of refills and date originally authorized;

(5) Number of refills remaining but not dispensed;

(6) Number of refills transferred.

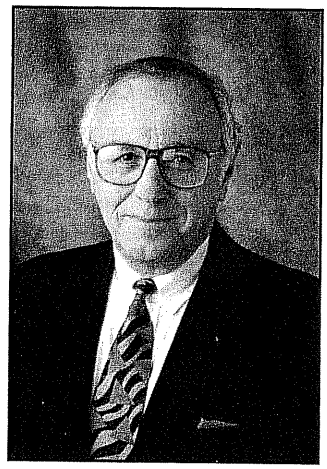
~~(g)~~ (f) The pharmacy must have written procedures that identify each individual pharmacist responsible for the filling of a prescription and a corresponding entry of information into an automated data processing system, or a manual record system, and the pharmacist shall create in his/her handwriting or through hand-initializing a record of such filling, not later than the beginning of the pharmacy's next operating day. Such record shall be maintained for at least three years.

Authority cited: Sections 4005, 4075 and 4114, Business and Professions Code. Reference: Sections 4005, 4019, 4027, 4050, 4051, 4052, 4075, 4114, 4116, 4117 and 4342, Business and Professions Code.

ATTACHMENT J

President's Report

I'm pleased to announce that Dave Thornton has been appointed as the Medical Board of California's (MBC) new executive director. He was selected on August 31, 2004 after the board reviewed over 80 highly qualified applicants. Mr. Thornton has been with the MBC for over 27 years and has served as the interim executive director since March 2004. His qualifications are impeccable and the Medical Board and its staff are very pleased and honored to welcome him as executive director.



Mitchell S. Karlan, M.D.
President of the Board

Congratulations to the nine members Governor Arnold Schwarzenegger recently appointed to our 21-member board, including two members who were reappointed to a second term (see page 1). I look forward to the fresh perspective and input of so many new members.

A major concern at this time is the purchasing of prescription drugs by patients directly from a foreign country or over the Internet. Physicians should be aware that federal law makes it illegal to import drugs into the U.S. that are not FDA approved. It is also illegal for any person other than the original manufacturer of a drug to import into the U.S. a prescription drug that was originally manufactured in the U.S. and sent abroad. Although it is currently **illegal**, an estimated 1 million Americans buy drugs from Canada, accounting for at least $1 billion in annual sales.

Drugs obtained from other countries (especially Canada and Mexico) may be of good quality but, on the other hand, a significant number of cases of counterfeiting, decreased potency and quality, and even fake substitutions have been recorded. If you order over the Internet, be cautious, as some businesses operate what may appear to be pharmacies, but are not pharmacies at all. Moreover, most drugs manufactured outside of the U.S. are not produced by a firm that has FDA approval.

The high cost of drugs is a serious public health issue. Some of our citizens cut back on food to pay for their drugs and others cut the pills in half to make them last longer. Our patients deserve prescription drugs that are affordable. Drug companies state that the high cost is due to research and development of new drugs. Marcia Angell, M.D., past editor of the *New England Journal of Medicine*, pointed out that in 2002, the biggest drug companies spent only about 14% of sales on research and development and 31% on what most of them call marketing and administration. Their profits are immense. In 2002, the combined profits of the 10 drug companies in the Fortune 500 were $35.9 billion. That was more than the profits for all the other 490 businesses put together, if you subtract losses from gains.

Even though it is illegal to bring various types of prescription drugs into the country under the provisions of the Federal Food, Drug, and Cosmetic Act, the FDA and Customs inspectors may not enforce the law when patients bring in small amounts for personal use (less than 90 days supply), or experimental drugs for major illnesses such as terminal cancer or AIDS.

The price of many of our drugs is excessive and, while this is largely a federal issue, we do need the help of our Legislature to get a base on the prices or allow us to safely order from Canada at 40 to 75% of the prices asked for in the U.S. Physicians should be allowed to become involved in this process without fear of civil, criminal or board disciplinary action. Of note, 14 pharmacies in California sued more than a dozen drug makers on August 26, 2004, accusing them of conspiring to keep U.S. prices well above those for the same drugs in Canada and other countries.

Two bills (SB 1149 (Ortiz) and AB 1957 (Fromer)) on the issue of importation of Canadian drugs are now before the Governor. He indicated in a letter of August 20, 2004 to U.S. Health and Human Services Director Tommy Thompson that he intends to veto them, stating, "...I am concerned that quick legislative fixes at the state level would be contrary to federal law and oversimplify the complex safety, trade, supply and pricing issues involved. ...I encourage the Bush Administration to aggressively pursue its discussions with our trading partners to achieve fairer pricing of pharmaceuticals in the international marketplace and an equitable distribution of the costs of drug research and development."

The Medical Board will follow and report any related state legislation.

I thank the dedicated and motivated members of the Medical Board for allowing me the rare pleasure and opportunity to serve the citizens and physicians of this state as president of this board.

Subject: fyi

11. Few U.S. Adults Have Purchased Medications Online, Study Says

Access this story and related links online:
http://www.kaisernetwork.org/daily_reports/rep_index.cfm?DR_ID=26197

Few U.S. adults have purchased prescription drugs online, despite "rising drug prices and increased pressure to import cheaper drugs from abroad," according to a Pew Internet and American Life Project study released on Sunday, Reuters/Washington Times reports (Reuters/Washington Times, 10/11). In the study, Pew researchers between May 15 and June 17 surveyed 2,200 adults ages 18 and older, 1,399 of whom were Internet users. The study found that only 4% of respondents had purchased prescription drugs online and that a smaller percentage had purchased medications from foreign pharmacies. According to the study, 62% of respondents said that they consider prescription drugs purchased online not as safe as those purchased from local pharmacies (Jesdanun, AP/Fort Worth Star-Telegram, 10/11). Twenty percent of respondents said that they consider prescription drugs purchased online as safe as those purchased from local pharmacies, the study found (Reuters/Washington Times, 10/11). The study found that respondents who had purchased prescription drugs online tended to have higher annual household incomes and at least six years of Internet experience. Most of those respondents said that they purchased medications from Web sites that required prescriptions and that they had prescriptions from their physicians, the study found (AP/Fort Worth Star-Telegram, 10/11). About 75% respondents who purchased prescription drugs online ordered medications to treat chronic conditions, such as arthritis and hypertension, and 25% ordered treatments for weight loss, improved sexual performance or other purposes, the study found.

Additional Results

According to the study, about 63% of respondents who were Internet users said that they received spam e-mail for sex-related prescription drugs, such as the erectile dysfunction medication Viagra, and 55% said that they had received spam e-mail for other treatments (Reuters/Washington Times, 10/11). The study also found that about 26% of respondents used the Internet to research prescription drugs or asked for help with such research (AP/Fort Worth Star-Telegram, 10/11).

Paul Riches, Chief of Legislation and Regulation
CA Board of Pharmacy
(916) 445-5014 ext. 4016

Paul Riches

10/12/2004 01:04 PM

cc:
Subject: fyi

2. New York Times Examines Bush's Statements on Prescription Drug Reimportation During Debate

Access this story and related links online: http://www.kaisernetwork.org/daily_reports/rep_index.cfm?DR_ID=26188

President Bush on Friday in the second presidential debate "hinted that he might allow imports of prescription drugs from Canada this year," although his administration "has consistently taken a strong stance against such imports" because of safety concerns, the New York Times reports (Pear, New York Times, 10/12). Bush on Sept. 13 during a speech in western Michigan called reimportation "an interesting idea" but said that he would not allow the practice until safety concerns are addressed (Kaiser Daily Health Policy Report, 9/14). In the debate, Bush said that his administration has not blocked reimportation and continues to study whether the federal government could ensure the safety of the practice (New York Times, 10/12). The 13-member HHS Task Force on Drug Importation has held a series of meetings as part of a study -- mandated by the new Medicare law -- on the safety of reimportation and the effect of the practice on prescription drug development. Task force members, who were appointed by HHS Secretary Tommy Thompson, can consult with other federal officials and earlier this year held six "listening sessions" with consumer advocates, health care purchasers, providers, health care industry representatives, international stakeholders and the public. The task force must report the results of the study to Congress by Dec. 1 (Kaiser Daily Health Policy Report, 10/7). Bush on Friday said, "It may very well be here in December you hear me say I think there's a safe way" to reimport prescription drugs. However, according to the Times, "until recently, the administration had not seriously considered the possibility that the FDA, with more employees and a larger budget, could police imports to guarantee their safety." The Bush administration in 2001 refused to allow reimportation and has opposed a bipartisan Senate bill (S 2328) sponsored by Sen. Byron Dorgan (D-N.D.) and others that would allow U.S. residents to purchase prescription drugs from Canada and other nations.

'Not That Different' From Kerry?

Dorgan said, "I was surprised to hear the president say he has not been blocking importation. Of course, he has. He and his administration have been blocking it for four years." Dorgan added that the Bush administration "has been doing the bidding of the pharmaceutical industry on this issue." However, Megan Hauck, deputy policy director for the Bush campaign, said, "The president has not blocked imports, but he is concerned about safety." She said, "As long as importation can be certified as safe, it can go forward." According to Hauck, the position Bush has taken on reimportation "is not that different" from the one taken by Democratic presidential nominee Sen. John Kerry (Mass.)

(New York Times, 10/12). Kerry on Sept. 11 in Missouri said that his administration would allow reimportation from Canada. Kerry said, "I just came from Minnesota the other day -- that's the gateway to Canadian drugs. And when I'm president, we're going to make all of America the gateway to the same drugs" (Kaiser Daily Health Policy Report, 9/13).

Paul Riches, Chief of Legislation and Regulation
CA Board of Pharmacy
(916) 445-5014 ext. 4016

Schwarzenegger Addresses Reimportation Legislation in Radio Interview

September 20, 2004

Gov. Arnold Schwarzenegger (R) on Friday in an interview with a Sacramento radio station "singled out" legislation that would direct the state to consider reimporting lower-cost, U.S. made prescription drugs from Canada, the Contra Costa Times reports. Schwarzenegger last month "strongly signaled" that he would veto the bills and offered lawmakers "an 11th hour compromise," according to the Times.

"I'm trying to do good things for the people, but [legislators] try to jam me so they can go back and say to their district: 'Look what this Republican governor did' so they can go and get their votes in November," Schwarzenegger said.

Sen. Deborah Ortiz (D-Sacramento), who sponsored one of the reimportation bills (SB 1149), said the measures will force Schwarzenegger to choose between drug companies and state residents seeking lower-cost medications, the Times reports. "Our job is not to cozy up to pharmaceutical companies but to help Californians," Ortiz said.

Dan Reeves -- chief of staff to Assembly Majority Leader Dario Frommer (D-Glendale), who sponsored another of the reimportation bills (AB 1957) -- said, "Don't say we're being unfair and mean to [Schwarzenegger] when we're standing up for what we believe in." Reeves added, "If he wants to be the people's governor he should just sign them" (Nissenbaum, Contra Costa Times, 9/18).

Please click here to return to the previous page.

Press Release

OFFICE OF THE GOVERNOR

GAAS:357:04
FOR IMMEDIATE RELEASE
08/20/2004

Text of Letter from Governor Schwarzenegger to Secretary Tommy Thompson

The following letter was sent by Governor Schwarzenegger to the Secretary of the U.S. Department of Health and Human Services today. A PDF version of the letter is attached.

August 20, 2004

The Honorable Tommy G. Thompson
Secretary
United States Department of
Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Secretary Thompson,

I am writing in regard to my concern about the growing cost of prescription drugs and my strong desire in identifying approaches that can make medicine more affordable for California's most at-risk consumers.

As we are all acutely aware, domestic prescription drug spending is growing at a rate that outpaces all other categories of health care expenditures. This escalation in cost is disturbing on a number of levels. In particular, I am concerned that rising drug prices push medicines beyond the reach of hard working low-income residents who lack health insurance and do not qualify for public programs.

Considerable attention in California and elsewhere has focused on efforts to allow states to import drugs from Canada in order to combat rising domestic prices. Support for such efforts reflect the depth and scope of public frustration with prescription drug costs and the belief that drug importation will yield reduced prices for consumers. While I share those frustrations, I am concerned that quick legislative fixes at the state level would be contrary to federal law and over-simplify the complex safety, trade, supply and pricing issues involved. Approaches that depend on uncertain future changes in federal law and policy will not bring much needed price reductions to consumers in the near term.

I want to help low-income uninsured Californians in the near term. We have been exploring approaches that offer not just the promise but the reality of meaningful discounts for prescription drugs. One approach is to establish a drug discount program for low-income uninsured residents through a state contract with a Pharmacy Benefit Manager (PBM). Under this approach, hard working Californians who lack insurance would simply be able to present a discount card at their local pharmacy to receive a discount on their prescription drugs. The PBM would negotiate discounted prices with drug manufacturers for program participants. The discount program would also incorporate the existing drug discount and free drug programs that the drug companies have not sufficiently publicized or made user-friendly for the population they are designed to serve.

Another approach we are exploring is to offer Medi-Cal (California's Medicaid program) prices to low-income uninsured residents. Using the state's purchasing power on behalf of California's Medi-Cal population, our program has successfully negotiated deep discounts from drug manufacturers. By extending Medi-Cal prices to targeted low-income uninsured residents, this approach would build upon our state's existing system of negotiated drug discounts, thus making relatively quick implementation possible. We recognize that this approach requires federal approval, so I have asked my Administration's Secretary for the Health and Human Services Agency, Kim Belshe to follow-up shortly with your office to arrange a meeting with your appropriate staff to discuss in greater detail this approach and how California can best move forward.

While the effort to secure meaningful prescription drug discounts for low-income residents is a necessary near term action, it is insufficient. Rather, it is time for the broader issues associated with the global marketplace to be considered and addressed. In that regard, I believe it is unfair and inappropriate that American consumers bear a disproportionate share of the expense of developing new pharmaceutical products that benefit the international community. I encourage the Bush Administration to aggressively pursue its discussions with our trading partners to achieve fairer pricing of pharmaceuticals in the international marketplace and an equitable distribution of the costs of drug research and development.

I look forward to working with you in this important effort.

Sincerely,

Arnold Schwarzenegger

Back to Top of Page

Please click here to return to the previous page.

THE STATE
Lawmakers Vote to Allow Drug Purchases From Canada
By Robert Salladay
Times Staff Writer

August 28, 2004

SACRAMENTO — Despite a large-scale lobbying effort by pharmaceutical companies and opposition from the Schwarzenegger administration, the Legislature on Friday gave final approval to a package of bills allowing cheaper drug imports from Canada.

The legislation puts California at the center of a national debate over the high cost of prescription drugs and could force Gov. Arnold Schwarzenegger to make a series of high-profile vetoes among the hundreds of bills sent to him before the end of the 2004 session.

"It's a far-reaching package to try to give some relief to seniors and the uninsured facing exorbitant prescription drug costs," said Anthony Wright, executive director of Health Access, a nonprofit advocacy group. "It would provide consumers with better information, more choices and, hopefully, cheaper drugs."

Although their actions are illegal, an estimated 1 million Americans already buy their drugs from Canadian pharmacies — costing U.S. pharmaceutical companies about $1 billion a year in lost revenue. Prices in Canada are as much as 40% cheaper, mostly because the government there caps prices.

Aides to the Republican governor already have dubbed some of the drug-importation legislation a "political ploy" and against the law because the federal government restricts drug imports from other countries. Schwarzenegger's health and welfare secretary said the bills would be "symbolic."

When Margita Thompson, a spokeswoman for the governor, was asked if Schwarzenegger would veto the importation bills, she said: "If legislation reaches his desk that would break the law, yes. Because right now, what we need to do is focus on what's right for the people and not breaking the law."

Among the bills sent to Schwarzenegger this week, two would set up a government-run Internet site that would compare prices between Canada and the United States, link consumers to Canadian

pharmacies and target shady and dangerous drug-selling websites.

Another bill would allow California pharmacies to sign contracts with Canadian pharmacies to purchase drugs for Medi-Cal and the AIDS drug-assistance program — saving $9 million a year in drug costs, advocates contend. The state would split the savings with the pharmacies.

Yet another measure would allow the state government to buy Canadian drugs in bulk for the prison, mental health and youth authority systems. That legislation could be more palatable to Schwarzenegger because it requires a federal waiver for approval.

Lawmakers also passed a measure that would allow state agencies to pool their purchasing power and negotiate for lower prescription drug prices.

"I think they hold extraordinary promise for bringing drug prices down," said Assemblyman Dario Frommer (D-Los Angeles). "The bulk-purchasing bills, for taxpayers, could be extremely meaningful. They could help us bring down drug prices. The website bills could provide immediate relief for consumers looking for answers."

According to Frommer's office, the state Medi-Cal program expects to have spent about $3.8 billion on prescription drugs for the 2003-04 fiscal year. The prison system pays about $125 million a year for drugs given to inmates, and the Public Employees' Retirement System spends $700 million every year, his office said.

Drug companies have said that consumers cannot trust the safety of drugs that flow through Canada and that comparing prices is misleading because of Canada's nationalized health system. They warn that siphoning money from the U.S. market would jeopardize the country's status as the world's leader in drug research and development.

And Republicans who argued against the bills said the U.S. Food and Drug Administration is the best agency to determine which drugs are safe.

"Ignoring the rule of law and encouraging illegal importation of drugs from Canada is the wrong way," said Assemblyman George Plescia (R-San Diego). "There is a reason that the federal government has a ban on drug importation. Drugs from foreign countries have not been proven safe."

Schwarzenegger last week proposed his own drug-pricing plan — allowing for seniors and others to pool their resources and buy at lower prices in bulk. The idea was summarily rejected by the Legislature. Lawmakers said it came too late in the session for in-depth consideration. They plan to take up his ideas next year, they said.

Consumer advocates have said Canadian imports are the best stopgap measure to allow senior citizens to get cheaper drugs right away. The FDA, they said, has looked the other way at five other states with Internet sites linking consumers to cheaper Canadian drugs, and some U.S. lawmakers have signaled a willingness to open the door to importation.

Biomedical research companies and national pharmaceutical manufacturers hired an army of lobbyists to defeat nearly a dozen bills before the Legislature this year. But their efforts now are turning to Schwarzenegger.

Drug makers, including biotech firms such as South San Francisco-based Genentech, have donated $186,000 to the governor since his election. That sum includes $100,000 from Pfizer Inc. in February to Schwarzenegger's California Recovery Team campaign committee. Pharmaceutical companies donated $103,000 to him during last year's recall campaign.

Thompson said Schwarzenegger makes his decisions based on the merits of legislation and nothing else. But Frommer and other lawmakers said the governor's contributions from drug companies will force him to make a critical decision as he considers the legislation.

"Californians are about to learn whether the governor is serious about standing up to special interests," Frommer said, "or is just

cc:
Subject: Rx Depot Drops Drug Importation Battle

FYI

Rx Depot Drops Drug Importation Battle

WASHINGTON - Rx Depot, a company that helped customers buy cheaper prescription drugs in Canada, gave up its legal battle Friday to reopen its storefronts that were ordered closed last year by a federal judge.

The Tulsa, Okla.-based company violated a law that allows only manufacturers to bring their drugs into the United States, U.S. District Judge Claire Eagan ruled. The judge acted at the request of the Food and Drug Administration (news - web sites).

The company, which operated in 25 states, faxed prescriptions and patients' medical histories to pharmacies in Canada, which then sent the drugs directly to patients.

Rx Depot had been appealing Eagan's order. It was unclear why the company dropped the appeal and agreed to a consent decree that makes the judge's order permanent.

Lawyers for the company did not immediately respond to requests for comment.

Dated: August 23, 2004

THE WALL STREET JOURNAL. ONLINE

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August 18, 2004

WSJ ONLINE/HARRIS INTERACTIVE HEALTH-CARE POLL

Drug Costs for Patients Seen as Greater Burden In U.S. Than in Canada

A WALL STREET JOURNAL ONLINE NEWS ROUNDUP
August 18, 2004

Almost all Americans believe the financial burden of drug costs for chronically ill patients is greater in the U.S. than in Canada, according to a recent Wall Street Journal Online/Harris Interactive Health-Care Poll.

The poll found, not-surprisingly, that generic drugs are seen by more Americans as having a very good or fairly good value (at 86%), compared with 26% who feel brand-name drugs represent a good value.

But while most Americans (73%) believe generic drugs are more expensive in the U.S. than in Canada, in many cases[1] the opposite is true, according to a recent Wall Street Journal article.

This misconception would help explain why 81% of those polled say chronically ill U.S. patients bear a greater financial burden because of the high costs of prescription drugs than patients in Canada.

"American angst about high drug prices in the U.S. is so strong that most people assume -- wrongly, in many cases -- that generic drugs cost more here than in Canada," says Humphrey Taylor, chairman of the Harris Poll at Harris Interactive.

"How would you rate each of the following in terms of the value for money they provide?"

Base: All Adults

Here are the results of the latest poll:

	Very Good Value	Fairly Good Value	Average Value	Somewhat Poor Value	Very Poor Value	Not Sure
Brand name prescription drugs	8%	18%	29%	19%	23%	3%
Over-the-counter						

(non-prescription) drugs	9	29	44	12	4	3
Vitamins and mineral supplements	8	25	41	13	5	6
Generic prescription drugs	25	36	25	7	2	2

Note: Numbers may not add up to 100% due to rounding.

* * *

"Please think about the last time you chose a generic drug over a brand name prescription drug. What was the main reason that you made that choice?

Base: All Adults

	Total
It was less expensive	40%
My doctor said it was just as good as a brand name alternative	14
My doctor prescribed it	13
The pharmacist said it was just as good as a brand name alternative	10
The pharmacist recommended it	4
I had taken this drug before	4
Some other reason	7
I have never chosen a generic drug over a brand name prescription drug	8

* * *

"Based on what you know or have heard, compared to Canada do you think the out-of-pocket costs for generic drugs in the US are . . .?"

Base: All Adults

	Total
Much/somewhat higher (NET)	73%
Much higher	44
Somewhat higher	28
About the same	9
Much/somewhat lower (NET)	6
Somewhat lower	4
Much lower	3

Not sure	12

Note: Numbers may not add up to 100% due to rounding.

* * *

"Overall, do you think that the amount of money chronically ill patients have to pay for their prescription drugs, including generics and brand name drugs, is a greater financial burden for patients in the U.S. or Canada?"

Base: All Adults

	Total
Greater financial burden to U.S. patients	81%
Greater financial burden to Canadian patients	3
About the same in both countries	4
Not sure	12

Methodology: This poll was conducted online in the U.S. between Aug. 6 and 10, 2004 among a nationwide cross section of 2,343 adults. Figures for age, sex, race/ethnicity, education, income and region were weighted where necessary to align with population proportions. Propensity score weighting was also used to adjust for respondents' propensity to be online. In theory, with probability samples of this size, one could say with 95% certainty that the results have a sampling error of ±3 percentage points of what they would be if the entire U.S. adult population had been polled with complete accuracy. This online sample was not a probability sample.

About Harris Interactive

Harris Interactive is a world-wide market research and consulting firm, best known for The Harris Poll and its use of the Internet to conduct scientifically accurate market research. For more information, see www.harrisinteractive.com[2]. To become a participant in The Harris Poll Online and join future online surveys, see www.harrispollonline.com[3].

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5. Enforcing Ban on Prescription Drug Reimportation 'Unsustainable,' But Practice Unlikely To Reduce Costs Substantially, Cato Institute Report Says

Access this story and related links online: http://www.kaisernetwork.org/daily_reports/rep_index.cfm?DR_ID=25112

A Cato Institute report released Wednesday states that legalizing the reimportation of drugs from other nations would "let the global marketplace sort out imbalances" in drug costs and force other countries to share the burden of funding new medical research, the Washington Post reports. The Cato report -- which represents a "direct conflict with [Cato's] allies in the Bush administration" -- notes that it is politically and economically "unsustainable" for federal regulators to control reimportation, according to the Post. In the report, Roger Pilon, Cato's vice president for legal affairs, states that drug makers need to earn large profits to guarantee investments in new treatments. However, Pilon adds that the drug industry should stop relying on the reimportation ban for profits and start negotiating higher prices with foreign customers. In the 20-page report, Pilon writes, "Removing the reimportation ban should not be seen ... as tantamount to reimporting foreign price controls." According to the report, legal reimportation would require companies to "shift some of the true costs of modern medicines" to what Pilon calls "free-rider" countries that pay low costs for drugs without having to invest in new research. The report noted that, with two million U.S. residents importing drugs illegally and a "diverse array" of lawmakers who support of lifting the reimportation ban, the current restrictions could present a political challenge to President Bush, the Post reports. "Senior citizens are a big voting bloc and a growing voting bloc," Pilon wrote, adding, "This is an issue of great concern to them." Russell Roberts, an economist at George Mason University, said that Pilon's plan would give U.S. residents "a better deal" but added that "it won't be so much in lower prices. It allows Americans to share the burden of future drug discoveries with a wider pool of payers" (Connolly, Washington Post, 8/4). The report is available online. Note: You must have Adobe Acrobat Reader to view this document.

The state pharmacy board says the proposal to list Canadian sources for medicines would violate federal law.
By Gabrielle Banks
Times Staff Writer

August 4, 2004

SACRAMENTO — State regulators are opposing one of the central ideas of Democratic legislators this year: to lower drug costs by identifying Canadian pharmacies where consumers can order them.

A Senate bill up for an Assembly committee vote today would require the state Board of Pharmacy to post names and Internet links to Canadian pharmacies on its website, as four other states do.

Days before the vote, the pharmacy board said the legislation would force it to endorse action that violates federal law against drug importation.

"We want patients to have access to safe medication," said Patricia Harris, the board's executive officer. But she said the board was uncertain about embracing something not approved by the U.S. Food and Drug Administration.

She said the board did not want to oppose the bill, "but this is not sanctioned by the FDA."

Although the pharmacy board does not report directly to Gov. Arnold Schwarzenegger, its position echoes some of the safety concerns expressed by the governor and the pharmaceutical industry.

The governor has said he wants to find ways to lower drug prices but is wary about Californians importing drugs from abroad if they would be violating federal laws. He has not taken a position on the pending legislation.

Pharmaceutical and biotech companies say they could lose profits that would otherwise go into research on new drugs if Californians buy pharmaceuticals from countries where they cost less.

The industries have spent more than $1 million lobbying against more than a dozen bills in the Legislature that would affect the way Californians get their prescriptions filled.

The industry's trade group, the Pharmaceutical Research and Manufacturers of America, has said that posting information about Canadian pharmacies on a state website would be illegal because the FDA does not permit bulk drug importation. The drug industry insists its prime concern is patient safety.

Peter Kellison, a lobbyist for the California Pharmacists Assn., said the group was opposed to the bill because there are not assurances that imported products "meet the same standards of safety and efficacy as those approved by the FDA."

The sponsors of SB 1149 hope an informational website would help Californians find places to purchase drugs more cheaply online.

The bill's author, Sen. Deborah Ortiz (D-Sacramento), said it included more safeguards than required by other states with similar websites. Under the bill, only pharmacies licensed by their Canadian province could be listed on California's website, and consumers would be required to have a prescription from a doctor licensed to practice in the United States.

Many Californians are already purchasing drugs from abroad, Ortiz said, adding, "Clearly, the pharmaceutical industry stands to lose outrageous and unfair profits in California."

The Legislature's lawyers examined the bill last month and concluded it would "not violate the importation or other provisions" of federal laws as long as the state only provided the names and contact information of Canadian pharmacies.

Democratic lawmakers have made the topic one of their top priorities for August, the last month of this year's session. Legislators are also considering a measure that would authorize the state to buy Canadian drugs in bulk for its healthcare programs for the poor.

Senate Democrats last week sent a fact-finding delegation of aides, activists for the elderly and others to Winnipeg and Vancouver to assess the quality of services at several mail-order pharmacies.

Narinder Singh, who directs 14 pharmacies for healthcare centers and prisons in Santa Clara County, said the pharmacies "we saw met or exceeded the standards for a mail-order pharmacy."

Mark Beach, a spokesman for AARP in California who also went on the trip, said, "Most Americans probably believe the Canadians have high standards. The pharmaceuticals industry is making a strong effort to cast aspersions on the safety of drugs from Canada."

Wisconsin, Minnesota, North Dakota and New Hampshire provide links to Canadian pharmacies on their state websites.

Although the FDA prohibits importation of medication from other countries, an estimated 1 million Americans do so anyway, according to Ortiz's office.
http://www.latimes.com/news/local/la-me-pharmacies4aug04,1,306200,print.story?coll=la-headlines-california

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FDA fears drugs a terror target

Acting commissioner says imported drugs biggest concern

WASHINGTON (AP) -- "Cues from chatter" gathered around the world are raising concerns that terrorists might try to attack the domestic food and drug supply, particularly illegally imported prescription drugs, acting Food and Drug Administration Commissioner Lester M. Crawford says.

In an interview with The Associated Press, Crawford said Wednesday that he had been briefed about al-Qaeda plans uncovered during recent arrests and raids, but declined further comment about any possible threats.

"While we must assume that such a threat exists generally, we have no specific information now about any al-Qaeda threats to our food or drug supply," said Brian Roehrkasse, spokesman for the Homeland Security Department.

Crawford said the possibility of such an attack was the most serious of his concerns about the increase in states and municipalities trying to import drugs from Canada to save money.

"We get our cues from chatter that occurs around the world, which is related to us by the intelligence community, and also from past incidents and things that happened domestically," he said.

Crawford noted the 1982 Tylenol case, in which packages of the extra-strength variety of the leading painkiller were removed from store shelves on Chicago's west side, filled with cyanide and returned to stores for purchase. Seven unsuspecting consumers were killed, and the incident prompted widespread adoption of tamperproof packaging.

"I would think that's something they would be looking at," Crawford said of terrorists. "Nothing like that has happened," he added. "But it is a source of continuing concern."

FDA is under mounting pressure -- and faces a lawsuit filed by the state of Vermont -- to soften its opposition to importing drugs from Canada, which is seen by many consumers and state and local government officials as a way to shave thousands to millions of dollars from drug bills.

The FDA has held fast, saying it is concerned about the safety and effectiveness of the illegally imported drugs. So far, however, the agency has done little more than issue warning letters. And Crawford said the agency has not decided whether to

vigorously defend itself against the Vermont lawsuit.

The agency's jitters about Canadian prescription imports are many. According to Crawford, some drugs are shipped without proper refrigeration, some have the wrong potency and some are counterfeit, lacking active ingredients.

Crawford's top concern is that terrorists could strike at drugs.

Commissioner briefed on terror threats

He said he was briefed about the al-Qaeda threats uncovered by recent arrests and raids. Asked whether the briefing covered potential terror strikes against products the agency regulates -- including food and drugs -- Crawford declined further comment.

Two recent product tampering episodes the agency faced this summer ended without injury or death.

Baby food, which Crawford said was probably singled out for its "shock" effect, was laced with ground castor beans in Irvine, California. The contamination source is unclear; no arrest has been made. Ricin, a deadly toxin, is made from castor beans.

And a shipment of lemons from Argentina allegedly impregnated with an unidentified "harmful biological substance" was barred from entry at the Port of Newark, New Jersey, on Aug. 6. The U.S. Coast Guard, Homeland Security Department and the FDA worked on the investigation, freezing the lemons to preserve the contaminant.

"There was nothing we could find in there," Crawford said.

On other issues, Crawford said:

- A second review links antidepressants with higher suicide rates among children. While outside observers who have read both reports say they contain enough detail for the FDA to recommend Prozac as the first drug of choice for depressed youths, Crawford said the agency will wait until its advisory committee meets in mid-September to give the FDA an expert basis for action.
- The agency approved two new injectable drugs, pentetate calcium trisodium and pentetate zinc trisodium, that speed the body's ability to rid itself of radioactive contamination. The drugs are the first products approved to treat contamination with plutonium, americium or curium, which could be released by a "dirty" bomb.
- Before year's end, the agency will provide regulations that define low-, reduced- or carbohydrate-free items. The FDA is leaning toward educating

the public by highlighting healthier foods with a "starburst" tag or color-coded label.

ATTACHMENT K

To the Members of the California State Senate:

I am returning Senate Bill 1149 without my signature.

A top priority of my Administration is to provide access to affordable prescription drugs. However, importing drugs from Canada or assisting residents in their efforts to do so would violate federal law and could expose the State to civil, criminal and tort liability. We all would like to see low-income uninsured residents have access to more affordable medicines, but measures such as this, over-simplify the complex safety, trade, supply and pricing issues involved in this marketplace. In light of these circumstances, I do not believe SB 1149 will bring the necessary relief to Californians who require assistance in accessing necessary medicines.

In an effort to bring significant price reductions to California's most at-risk consumers, my Administration put forward "California Rx" that seeks to provide real assistance to these Californians. California Rx represents an approach that harnesses the purchasing power of low-income seniors and uninsured Californians up to 300% of the federal poverty level ($47,000 for a family of three) to secure meaningful discounts in prescription drug costs. My Administration has begun negotiations with pharmaceutical companies regarding their participation in California Rx. While I am encouraged by the concrete commitments made by some members of the industry, I am disappointed that many companies have not yet stepped up and offered meaningful discounts for this population. Over the next six weeks, I will continue negotiations to secure significant discounts for California's low-income uninsured, and I hope to move forward with a legislative proposal in January 2005 to implement California Rx. If, however, specific companies and the industry as a whole are not willing to provide a real solution to this problem, I will work closely with the State Legislature to develop an approach that guarantees significant reductions in prescription drug prices for California's low-income uninsured residents.

Come January, I will propose legislation that will bring lower-cost prescription drugs to California's most vulnerable residents. I am still hopeful that California Rx will be the vehicle to secure those price reductions, but for a voluntary, negotiated model such as California Rx to work, the drug companies must come forward and negotiate in good faith. I call upon the companies to help solve this problem through California Rx; but if I cannot rely on the good faith negotiations of the industry, I will use all the options at my disposal to secure lower-cost prescription drugs for low-income, uninsured Californians.

For these reasons I am returning this bill without my signature.

Sincerely,

Arnold Schwarzenegger

CALIFORNIA HEALTH AND SAFETY CODE
DIVISION 112
CALIFORNIA STATE PHARMACY ASSISTANCE PROGRAM

130600. (a) This division shall be known, and may be cited as, the California State Pharmacy Assistance Program.

(b) For the purposes of this division, the following definitions apply:

(1) "Program" means the California State Pharmacy Assistance Program.

(2) "Department" means the State Department of Health Services.

(3) "Resident" means a California resident pursuant to section 17014 of the Revenue and Taxation Code.

(4) "Recipient" means a resident that has completed an application and has been determined eligible for the program.

(5) "Prescription drug" means any drug that bears the legend: "Caution: federal law prohibits dispensing without prescription," "Rx only," or words of similar import.

(6) "Fund" means the California State Pharmacy Assistance Program Fund.

(7) "Private discount drug program" means a prescription drug discount card or manufacturer patient assistance program that provides discounted or free drugs to eligible individuals. For the purposes of this division, private discount drug programs are not considered insurance or a third-party payer program.

130601. (a) There is hereby established the California State Pharmacy Assistance Program.

(b) The department shall administer the program by contracting with a private third party vendor to perform the Department responsibilities enumerated in this article. The Department may, if necessary, directly negotiate rebates with drug manufacturers or perform other responsibilities.

(c) Any California resident may enroll in the Program if determined eligible pursuant to section 130602.

130602. (a) To be eligible for the program, an individual must meet all of the following requirements at the time of application or reapplication for the program:

(1) Be a resident;

(2) Have family income, as reported pursuant to 130602.1, that does not exceed three hundred percent of the federal poverty guidelines, as revised annually by the United States department of Health and Human services in accordance with section 673(2) of the "Omnibus Budget Reconciliation Act of 1981," 95 Stat. 511, 42 U.S.C. 9902, as amended;

(3) Not have outpatient prescription drug coverage paid for in whole or in part by any of the following:

(A) A third-party payer;
(B) The Medi-Cal program;
(C) The children's health insurance program;
(D) The disability medical assistance program;
(E) Another health plan or pharmacy assistance program that uses state or federal funds to pay part or all of the cost of the individual's outpatient prescription drugs. Notwithstanding any provision of this division to the contrary, people enrolled in Medicare may participate in this program to the extent allowed by federal law for prescription drugs not covered by Medicare.

(4) Not have had outpatient prescription drug coverage specified in (3) of this subdivision during any of the 3 months preceding the month in which the application or reapplication for the program is made, unless any of the following applies:

(A) The third-party payer that paid all or part of the coverage filed for bankruptcy under federal bankruptcy laws.
(B) The individual is no longer eligible for coverage provided through a retirement plan subject to protection under the "Employee Retirement Income Security Act of 1974," 88 Stat. 832, 29 U.S.C. 1001, as amended.
(C) The individual is no longer eligible for the Medi-Cal program, children's health insurance program, or disability medical assistance program.

(b) Application and a simple annual reapplication for the program shall be made pursuant to section 130602.1. An applicant may apply or reapply on behalf of the applicant and the applicant's spouse and children. The guardian or custodian of an applicant may apply or reapply on behalf of the applicant.

130602.1 (a) The department shall develop an application form for the determination of a resident's eligibility for the program.

(b) The application, at minimum, shall do the following:

(1) Specify the information that an applicant or the applicant's representative must include in the application about the applicant;

(2) Require that the applicant attest that the information the applicant provides in the application is accurate to the best knowledge and belief of the applicant;

(3) Include a statement printed in bold letters informing the applicant that knowingly making a false statement is punishable as perjury.

(4) Specify the application fee due upon application submission. The application fee shall be $10 for the initial enrollment. The initial application may be made at participating pharmacies or through the private third party vendor. The third party vendor shall develop the renewal application, shall utilize a secure Internet based application process for this program, and shall provide a call center to assist people in enrolling.

(c) In assessing the income requirement for program eligibility, the department shall use the income information reported on the application and not require additional documentation.

(d) Application and annual reapplication may be made at any pharmacy participating in the program. The pharmacy completing the application shall keep the application fee as reimbursement for its cost of processing the application. If it is determined the applicant is already enrolled in the program, the pharmacy shall return the fee to the applicant and inform the applicant of their current status as a recipient.

(e) The department may provide for a secure electronic application process that can be used by pharmacies to enroll applicants in this program.

(f) During normal business hours, the department shall make a determination of eligibility within 4 hours of receipt of the application. The Department shall mail the recipient an identification card no later than 4 days after eligibility has been determined.

(g) For applications submitted through a pharmacy, the department may issue a recipient identification number for eligible applicants to the pharmacy for immediate access to the program.

130602.2. (a) The department shall attempt to execute agreements with private discount drug programs to provide a single point of entry for eligibility determination and claims processing for drugs available in those private discount drug programs.

(b) An applicant may be required to provide additional information to determine the applicant's eligibility for other discount card and patient assistance programs.

(1) An applicant shall not be, in any circumstance, required to participate in, or to disclose information that would determine the applicant's eligibility to participate in these private discount drug programs in order to participate in the program provided in this division.

(2) Notwithstanding paragraph (1), an applicant may voluntarily disclose or provide information that may be necessary to determine eligibility for participation in a private drug discount program.

(c) For those drugs available pursuant to subdivision (a), the department shall develop a system that provides a recipient with the best prescription drug discounts that are available to them through this program or through private discount drug programs.

(d) The recipient identification card issued pursuant to 130602.1(f) shall serve as the single point of entry for drugs available pursuant to subdivision (a) and shall meet all legal requirements for a health benefit card.

130602.3. (a) To the extent that funds are available, the department shall conduct outreach programs to inform residents about this program. No outreach material shall contain the name or likeness of a drug or the likeness of an elected state official. The name of the organization sponsoring the material pursuant to subdivision (b) may appear on the material once and in a font no larger than 10 point.

(b) The department may accept on behalf of the state any gift, bequest, or donation of outreach services or materials to inform residents about this program. Neither Section 11005 of the Government Code nor any other law requiring approval by a state officer of a gift, bequest, or donation shall apply to these gifts, bequests, or donations. For purposes of this section, outreach services may include, but shall not be limited to, coordinating and implementing outreach efforts and plans, and outreach materials may include, but shall not be limited to, brochures, pamphlets, fliers, posters, advertisements, and other promotional items.

(c) An advertisement provided as a gift, bequest, or donation pursuant to this section shall be exempt from the provisions of Article 5 (commencing with Section 11080) of Chapter 1 of Part 1 of Division 3 of Title 2 of the Government Code.

130603. (a) Any pharmacy licensed pursuant to Chapter 9 of the Business and Professions Code may participate in the program provided for under this division.

(b) Any drug manufacturer may participate in the program provided for under this division.

130604. (a) This division shall apply only to prescription drugs dispensed to non-institutionalized recipients.

(b) The amount a recipient pays for a drug within the program shall be equal to the participating provider's usual and customary charge or the pharmacy contract rate pursuant to (d), less a program discount for the specific drug or an average discount for a group of drugs or all drugs covered by the program.

(c) In determining program discounts on individual drugs, the department shall take into account the rebates provided by the drug's manufacturer, the state's share of the discount and any amount provided to a contractor pursuant to sections 130604.1 and 130607.

(d) On behalf of the department, the private third party vendor may contract with participating pharmacies for a rate other than the pharmacies' usual and customary rate.

(e) The private third party vendor shall provide a claims processing system that:

(1) Provides the price charged pursuant to (b).

(2) Provides the pharmacy with the dollar amount of the discount to be returned to the pharmacy.

(3) Provides a single point of entry for access to private discount drug programs pursuant to 130602.2.

(4) Provides drug utilization review warnings to pharmacies consistent with the drug utilization review standards outlined in Section 1927 of the federal Social Security Act (42 U.S.C. Sec. 1396r-8).

(f) The private third party vendor shall pay a participating pharmacy the discount provided to recipients pursuant to subdivision (b) by a date that is not later than two weeks after the claim is received by the department.

130604.1. (a) The department or the private third party vendor shall attempt to negotiate drug rebate agreements with drug manufacturers to provide for program drug discounts.

(b) The drug rebate agreements shall:

(1) Specify which of the manufacturer's drugs are included in the agreement.

(2) Permit the department to remove a drug from the agreement in the event of a dispute over the drug's utilization.

(3) Require that the manufacturer make a rebate payment to the department for each drug specified under division (b)(1) of this section dispensed to a recipient.

(4) Require that the rebate payment for a drug shall be equal to the amount determined by multiplying the applicable per unit rebate by the number of units dispensed.

(5) Require that the definition of a unit comply with the standards set by the National Council for Prescription Drug Programs.

(6) Require that the manufacturer make the rebate payments to the department on at least a quarterly basis.

(7) Require the manufacturer to provide, upon request by the department, documentation the department can use to validate that the per unit rebate provided complies with (b)(4).

(8) Permit a drug manufacturer to audit claims for their drugs provided in the program. Claims information provided to manufacturers shall comply with all federal and state privacy statutes to protect a recipient's individual health information.

(9) Develop a program to prevent the occurrence of fraud in this program.

(10) Develop a mechanism for recipients to report problems or complaints regarding the program.

(c) The department or third party vendor shall seek to contract for drug rebates equal to the Medicaid best price. For those drugs most commonly used, the department or third party vendor shall seek to contract for drug rebates lower than the Medicaid best price.

(d) To obtain the most favorable discounts, the department may limit the number drugs available within the program.

(e) No less than 95 percent of the drug rebates negotiated pursuant to this section must go to reducing the cost of purchasing buying drugs by the participants in the program. The legislature shall annually appropriate an amount to cover the state's share of the discount provided by this subdivision.

(f) The department and third party vendor may collect prospective rebates from drug manufacturers for payment to pharmacies pursuant to section 130604(f). The amount of the prospective rebate shall be contained in drug rebate agreements executed pursuant to 130604.1.

130605. (a) The department shall deposit all payments it directly receives pursuant to Sections 130604.1 and 130602.3 into the California State

Pharmacy Assistance Program Fund, which is hereby created in the State Treasury.

(b) Notwithstanding Section 13340 of the Government Code, the fund is hereby continuously appropriated to the department without regard to fiscal years for the purpose of providing payment to participating pharmacies pursuant to Section 130604 and for defraying the costs of administering this division. Notwithstanding any other law, no money in the fund is available for expenditure for any other purpose or for loaning or transferring to any other fund, including the General Fund.

130409. (a) The department may hire any staff needed for the implementation and oversight of the program created by this division.

(b) The department shall contract with a public or private entities, such as pharmacy benefit management companies, to implement or administer the program completely or in part.

(1) Drug rebate contracts negotiated by the third party vendor shall be subject to review by the department. The department shall be able to cancel a contract that it finds not to be in the best interest of the state or the recipients of the program.

(2) The third party vendor may directly collect rebates from manufacturers in order to facilitate the payment to pharmacies pursuant to section 130604(f). The department shall develop a system to prevent diversion of funds collected by the entity.

(3) Entities must issue monthly reports to the department that, at minimum, provide:

(A) Drug utilization information.

(B) Amount paid to pharmacies.

(C) Amount of rebate collected from manufacturers.

(D) Summary of the problems or complaints received regarding the program.

(E) Information provided in (A), (B), and (C) shall be at the national drug code level.

(c) Payment of fees to contract entities pursuant to subdivision (b) shall be from the fund.

130608. (a) The department shall seek and obtain confirmation from the federal Centers for Medicare and Medicaid Services, that the program created by this division complies with the definition of a state pharmaceutical assistance program pursuant to Section 1927 of the federal Social Security Act (42 U.S.C. Sec. 1396r-8) and that discounts provided under the program are exempt from Medicaid best price.

130609. Contracts executed for the purposes of this division are exempt from Part 2 (commencing with Section 10100) of Division 2 of the Public Contract Code. The Department must select the third party vendor through a competitive procurement. Contracts with pharmacies and pharmaceutical manufactures may be done on a bid or non-bid basis.

1306010. The Department may cancel this program if it determines that there are insufficient discounts to participants to make this program viable, that there are an insufficient number of applicants or if the Department is unable to find a responsible third party vendor to run this program.

The Legislature hereby appropriates from the General Fund to the department the amount of $3,000,000 to fund staff and contract cost for this program.

Notwithstanding Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code, the director may implement this article, in whole or in part, by means of a provider bulletin, or other similar instructions, without taking regulatory action.

ATTACHMENT L

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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

MORE SB 151 QUESTIONS AND ANSWERS

Q Can a California pharmacy fill a controlled substance prescription from an out of state prescriber for a patient in California?

A California Code of Regulations section 1717(d), in accordance with Business and Professions Code section 4005(b), allows written and oral prescriptions from out-of-state prescribers. Pharmacies must verify the prescription. The pharmacist should use his or her best professional judgment when filling out-of-state prescriptions.

Q Can the new tamper-resistant security prescription form be preprinted with more than one prescriber; for example, a group practice setting?

A Yes. The forms should include check boxes or some other means to identify the specific prescriber's name, category of licensure, state license number, and DEA number.

Q What should a prescriber do if he or she is out of the triplicate prescription forms and/or has not yet received his or her new tamper-resistant security prescription forms but needs to write a controlled substance prescription?

A The Board of Pharmacy is most concerned that the healthcare needs of legitimate patients be met during the transition to the new tamper-resistant prescription form and has issued a memo dated August 11, 2004, that supports prescribers' temporary use of the exception to the special form requirement in Health and Safety Code section 11167. Prescribers must make good faith efforts to obtain the new prescription forms in compliance with the law.

Prescribers must write "11167 exemption" on the prescription and pharmacists' should exercise their professional judgment when filling these prescriptions with the highest priority given to evaluating whether a prescription is authentic and issued for a legitimate medical purpose.

Health and Safety Code section 11167 allows, in an emergency, where failure to issue the prescription could result in loss of life or intense suffering, an order for a controlled substance to be dispensed on an oral, faxed or plain paper prescription as long as the order contains all of the required information. Written orders must be signed and dated by the prescriber. The pharmacist must reduce oral or faxed prescription orders to hard copy form. The prescriber is required to provide a written prescription on the appropriate prescription form by the 7th day following the order. The pharmacist must notify the Bureau of Narcotic Enforcement within 144 hours of the prescriber's failure to do so, including the date and method of notification.

Q What are the quantity check-off boxes on the new tamper-resistant prescription forms?

A The quantity check-off boxes are a security feature that ensures the quantity, for which the prescription is written, is not tampered with in any way. The prescriber writes the prescription as usual, including the quantity, in the body of the prescription. In addition, the prescriber checks the box next to the applicable quantity range confirming the quantity for each prescription written. If the prescription is for anything other than tablets or capsules, the prescriber must also designate the units referenced in the quantity range.

Q How does a prescriber mark the quantity check-off boxes on the new tamper-resistant security prescription form when writing a prescription for multiple drugs on one prescription form?

A Some of the new tamper resistant prescription forms provide separate sections for writing multiple drug prescriptions, which include separate quantity check-off boxes for each. However, some form designs include only one set of quantity check-off boxes. Prescribers' check the appropriate quantity range confirming the quantity for each prescription written. For example, if a prescriber writes one prescription for 100 tablets and, on the same form, writes another prescription for 25 tablets, the prescriber would check the quantity ranges 75 to 100 and 25 to 49. If the quantity of more than one prescription falls within the same range, simply check the quantity range once. For example, if the prescriber writes three prescriptions and two are for 100 tablets each and one is for 300 tablets, the prescriber would check the quantity ranges 75–100 and 151 and over.

Q Does my facility qualify as a "licensed health care facility" so that we can order "institution" style tamper-resistant prescription forms?

A *"Licensed health care facility"* means a facility licensed pursuant to Article 1 (commencing with section 1250) of Chapter 2 of Division 2 of the California Health and Safety Code, such as, a general 24-hour acute care hospital, acute psychiatric hospital, skilled nursing facility, or intermediate care facility.

Q Where can I find a list of all controlled substances including the drug schedule?

A California controlled substance standards and drug schedules, along with a corresponding list of drugs, are found in Chapter 2 of Division 10 of the California Health and Safety Code (commencing with section 11053). A Federal list of controlled substances, including the drug schedule, can be found on the Drug Enforcement Administration's website at http://www.deadiversion.usdoj.gov/schedules.

Q Can a Schedule II controlled substance prescription be refilled?

A No. Prescribers should mark zero (0) or no refills (NR). The new tamper-resistant forms include an area for refills because the form can be used for any controlled or non-controlled substance prescription.

Q Can more than one Schedule II medication be written on the same form?

A Yes. As long as the new prescription form has the statement at the bottom that reads, "Void if the number of drugs is not noted" and a line provided for the physician to write in the number of drugs prescribed.

Q Can a pharmacist fill a prescription for a controlled substance if an error is found on the prescription?

A The prescriber's signature and the date written are required to be written by the prescriber. Everything else can be written by the prescriber or his or her agent. Therefore, the pharmacist can make changes to any other information on the prescription as long as the pharmacist verifies the change with the prescriber first.

Q Is the pharmacy still required to keep a separate record for Schedule II prescriptions filled? If so, what if there is more than one prescription on the form?

A Pharmacies are required to keep a separate record in the pharmacy of Schedule II prescriptions filled regardless of whether or not the prescription includes other non-Schedule II medications. Additionally, the pharmacy is required to submit the Schedule II prescription information to CURES electronically or on disk, and effective January 1, 2005, must submit both Schedule II and III prescription information to CURES.

Q Can a prescriber electronically transmit a Schedule III through V controlled substance prescription from a computer or personal digital assistant (PDA) to a pharmacy's computer or fax machine?

A Yes. Advice from the Drug Enforcement Administration in a letter from Patricia M. Good, Chief of the Liaison and Policy Section, Office of Diversion Control for the U.S. Department of Justice dated September 28, 2001, states that current DEA regulations allow for Schedule III, IV, or V controlled substances that are electronically created or transmitted, which includes PDA's, either directly to a computer or via facsimile machine, be treated as an oral prescription. This means the prescription must be reduced to hard copy form by the pharmacist and retained for at least three years. Additionally, a pharmacist that receives an electronically transmitted prescription via facsimile, or other methods, must ensure the validity of the prescription prior to dispensing the controlled substance (Title 21, Code of Federal Regulations section 1306.21).

Electronically transmitted prescriptions, including those sent via PDA, must contain an electronic signature of the prescriber. Pharmacies must ensure the authenticity, integrity, non-repudiation, and confidentiality of the document. Authentication means ensuring that the prescriber is the person he or she purports to be. Integrity means ensuring that both the document and the signature have not been altered in the course of transmission. Non-repudiation means ensuring that a party to the transaction cannot later disclaim it. Moreover, a pharmacist has an affirmative obligation to verify a prescription when appropriate to do so.

The pharmacy must also ensure that a prescription has been electronically transmitted to the pharmacy of the patient's choice. This may be done a number of ways, including, but not limited to, an affirmative statement on the prescription that the prescriber advised the patient of this right.

ATTACHMENT M

5 Office conferences were held this quarter

Citation and Fine Statistics for July 1, 2004 – September 21, 2004

Contested Citations Office Conference

Requested	Scheduled	Appeared	Affirmed	Modified	Dismissed	Reduced to letter of admonishment	Withdrawn
192	184	148	26	34	50	4	3

Amount of fines issued this quarter $108,200.00

Amount of fine collected this quarter $12,225.00

Citation Breakdown by license type

Total issued	RPH with fine	RPH no fine	PHY with fine	PHY no fine	PIC with fine	PIC no fine	TCH with fine	TCH no fine
188	29	2	50	34	34	15	6	1

Miscellaneous Citation Breakdown by license type

Wholesalers	Exemptee's in charge	Clinics	Hypo permits	Hospital pharmacy	Unlicensed Premises	Unlicensed person
2	2	3	1	2	6	1

Top Ten Violations by license type

Pharmacists	%	Pharmacies	%	Pharmacists in charge	%
1716 - Variation from prescription	70%	1716 - Variation from prescription	37%	1716 - Variation from prescription	17%
1715.5 - Implementation of electronic monitoring of schedule II prescriptions	6%	1714(b) - Operational standards and security; pharmacy responsible for pharmacy security	12%	4125/1711 - Quality assurance program	15%
17612(a) - No pharmacist shall compound or dispense any prescription, which contains any significant error or omission...	6%	4125/1711 - Quality assurance program	11%	4342/USP 25th edition page 10 - Actions by board to prevent sales of preparations or drugs lacking quality or strength	12%
1715 - Self-assessment of a pharmacy by PIC	3%	4342/USP 25th edition page 10 - Actions by board to prevent sales of preparations or drugs lacking quality or strength	8%	1715(a) - Self-assessment form of a pharmacy by the pharmacist in charge; shall complete a self-assessment of the pharmacy's compliance with federal and state pharmacy law	10%
1716/1761 - Variation from Rx / Erroneous Rx	3%	1715(a) - Self-assessment form of a pharmacy by the pharmacist in charge; shall complete a self-assessment of the pharmacy's compliance with federal and state pharmacy law	7%	1304.04(f) - Each registrant shall maintain inventories and records of controlled substances	8%
1714(d) - Operational standards and security; pharmacy responsible for pharmacy security	3%	4113(a)/1709.1 – Pharmacist in charge, notification to the board, Responsibilities /Designation of a pharmacist in charge	7%	1714(c) - Operational standards and security; the pharmacy must be maintained in a sanitary condition	8%
4063 - Refill of prescription for dangerous drug or device; prescriber authorization	3%	1716/1761 - Variation from Rx / Erroneous Rx	6%	1714(d) - Operational standards and security; pharmacy responsible for pharmacy security	8%
1707.1 - Duty to maintain medication profiles	3%	1707.1 - Duty to maintain medication profiles	5%	1707.1 - Duty to maintain medication profiles	6%
1707.3 - Preprinted, multiple checkoff prescription blanks	3%	1304.04(f) - Each registrant shall maintain inventories and records of controlled substances		1715.5(a)(b) - Self-assessment by the pharmacist in charge; / within 30 days ...	6%
4125/1711 - Quality assurance program	3%	1715.6 - Reporting drug loss	4%	1716/1761 – Variation from prescription/Erroneous or uncertain prescriptions	6%

Citation Statistics from May 15, 2001 – September 21, 2004

1843 citations have been issued with fines totaling $1,560,054.00.

135* of these citations totaling **$310,950.00**, in fines, have not been collected.

Of the **135: (see all bolded totals)**

19 citations totaling **$125,500.00**, have been closed as uncollectible.

12 fines totaling **$9,250.00**, have been added to license renewal fees and the licenses have been placed on hold.

25 citations totaling approximately **$44,230.00**, are currently under review for possible renewal hold.

27 citations totaling $30,750.00 fines have been issued to canceled/unlicensed technicians.

12 of these citations totaling $3,875.00 have been collected.

15 citations issued to canceled/unlicensed technicians totaling **$26,875.00**, remain uncollected.

29 citations totaling $41,620.00 have been issued to unlicensed premises.

12 of these citations totaling $6,275.00 of these fines have been collected.

17 citations issued to unlicensed premises totaling **$35,345.00**, remain uncollected.

92 citations have been issued with a fine to canceled premise licenses totaling $116,400.00.

45 of these fines totaling $46,650.00 have been collected.

47 citations issued to canceled premise licenses totaling **$69,750.00**, remain uncollected

* This number represents less than 7.5% of the citations issued.

ATTACHMENT N

U. S. Department of Justice
Drug Enforcement Administration

www.dea.gov

Washington, D.C. 20537

AUG 27 2004

Ms. Patricia Harris
Executive Officer
California State Board of Pharmacy
400 R Street, Suite 4070
Sacramento, California 95814

Dear Ms. Harris:

The Drug Enforcement Administration's (DEA), Office of Diversion Control, is in the process of changing the style and appearance of the DEA Controlled Substance Registration Certificate. As of October 1, 2004, the revised Certificate of Registration will consist of two parts: one that can be displayed on the wall and a smaller wallet size version (see enclosure). The certificate will have an imbedded watermark logo, which will provide authentication of the certificate and also deter counterfeiting.

Registrants that are currently allowed to renew their DEA registration via the Diversion Control Program's website (i.e., Retail Pharmacies, Hospitals, Practitioners, Mid-level Practitioners and Teaching Institutions) may print their Certificate of Registration upon completion of the registration renewal process as long as no changes have been made to their registration since their last renewal. The Diversion Control Program's website may be accessed at www.DEAdiversion.usdoj.gov. The DEA will continue to send Certificates of Registration via the United States Postal Service to all new registrants and all other DEA registrants renewing their DEA registration.

At this time we are seeking your organization's assistance with informing your members of the new revised DEA certificate. Should you have any questions, please feel free to contact Lynn Bossert, Program Analyst, Liaison and Policy Section, at (202) 307-7297.

Sincerely,

Patricia M. Good

Patricia M. Good, Chief
Liaison and Policy Section
Office of Diversion Control

Enclosure

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
BR0123456	12-31-2007	PAID

SCHEDULES	BUSINESS ACTIVITY	DATE ISSUED
2,2N 3,3N,4,5	PRACTITIONER	11-23-2004

JANE D REGISTRANT
1234 MAIN AVE
PO BOX 1234

ANYCITY US 12345-0123

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON, D.C, 20537

Sections 304 and 1008 (21 U.S.C. 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacturer, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, BUSINESS ACTIVITY, OR VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (11/03)

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON, D.C, 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
BR0123456	12-31-2007	PAID

SCHEDULES	BUSINESS ACTIVITY	DATE ISSUED
2,2N 3,3N,4,5	PRACTITIONER	11-23-2004

JANE D REGISTRANT
1234 MAIN AVE
PO BOX 1234

ANYCITY US 12345-0123

Sections 304 and 1008 (21 U.S.C. 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacturer, distribute, dispense, import or export a controlled substance.

Form DEA-223 (11/03)

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, BUSINESS ACTIVITY, OR VALID AFTER THE EXPIRATION DATE.

ATTACHMENT O

California State Board of Pharmacy
400 R Street, Suite 4070, Sacramento, CA 95814-6237
Phone (916) 445-5014
Fax (916) 327-6308
www.pharmacy.ca.gov

STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
Arnold Schwarzenegger, GOVERNOR

ENFORCEMENT COMMITTEE MEETING

Meeting Summary
September 29, 2004

Hilton Burbank Airport & Convention Center
2500 Hollywood Way
Burbank, CA 91505

Present: William Powers, Chair
Stan Goldenberg, R.Ph., Board President and Member
David Fong, Pharm.D.

Staff: Patricia Harris, Executive Officer
Virginia Herold, Assistant Executive Officer
Robert Ratcliff, Supervising Inspector
Judi Nurse, Supervising Inspector
Dennis Ming, Supervising Inspector
Joan Coyne, Supervising Inspector
Board of Pharmacy Inspectors
Joshua Room Deputy Attorney General

Call to Order

Enforcement Committee William Powers called the meeting to order at 9:30 a.m.

Reimportation of Prescription Drugs from Canada

The Enforcement Committee was provided background information on activities in this area since the last board meeting. It was noted that the Governor had not yet acted on the various legislative proposals that would assist Californians in obtaining prescription drugs from Canada. The committee was also given a copy a letter from Governor Schwarzenegger to Secretary Tommy Thompson dated August 20, 2004, expressing concern about the growing cost of prescription drugs and his strong desire in identifying approaches that can make medicine more affordable for California's most at-risk consumers. In the letter, he also encouraged the Bush Administration to aggressively pursue its discussions to achieve fairer pricing of pharmaceuticals in the international marketplace and an equitable distribution of the costs of drug research and development.

In an effort to do this, the Governor put forward "California Rx" that seeks to provide assistance to these Californians. The proposal would establish a drug discount program for low-income uninsured residents through a state contract with a Pharmacy Benefit Manager (PBM). The intent is for Californians that lack insurance would be able to present this discount card at their local pharmacy to receive a discount on their prescription drugs. The PBM would negotiate discounted prices with drug manufacturers for program participants. The program would be available to low-income seniors and uninsured Californians up to 300% of the federal poverty level ($47,000 for a family of three) to secure meaningful discounts in prescription drug costs.

There was general discussion regarding "California Rx". The board was strongly encouraged to take an active role in the development of this proposal and asked that it be discussed at the October board meeting. It was noted that while a bill hasn't been introduced, the information will be provided as part of the Legislative/Regulation Committee's report and would be included if a bill is introduced next year. The board is very sensitive to this issue and is tasked with balancing consumer access to affordable prescriptions against the safety and effectiveness of drugs obtained from foreign sources. The intent of the Governor's proposal, "California Rx" is to improve access as an alternative to importation.

It was reported that Senate Health and Human Services Committee held on an informational hearing on September 21st. The hearing included an in-depth overview of "California Rx", the timeline for implementation, and the estimated cost savings. Representatives were invited to present a critical analysis of the proposal, its feasibility and overall benefit when compared to some of the drug importation proposals that were introduced over the past legislative session.

It was suggested that for future meetings, this agenda topic be titled "Importation of Prescription Drugs" since the issue is more than the reimportation of prescription drugs from Canada.

Proposed Legislative Change to Update the Law Regarding the Pharmacist Recovery Program (Bus. & Prof. Code sec. 4360 – 4373)

Executive Officer Patricia Harris reviewed the draft proposal for updating the statutory provisions related to the Pharmacists Recovery Program (program). She explained that while most of the proposed changes are minor, technical revisions to more closely conform the statute to the current operation of the program, some of the changes are substantive.

Ms. Harris noted that the most substantive change effects section 4362. This section specifies who is eligible to enter the program and the terms of entry into the program. First, a licensee can be referred to the program instead of or in addition to disciplinary action. Second, a licensee can enter the program voluntarily. This largely reflects current operation of the program.

The substantial change made is that licensees that enter the program voluntarily will not have their identities withheld from the board. Current law indicates that such "self-referrals" are confidential and the board is generally not informed of their identities. This "confidentiality" can be voided if the program administrator believes the licensee may present a threat to the

public. However, participants sign disclosure agreement upon entering the program that permits the program to release their identity to the board. This statutory change would conform to existing practice by the program.

The draft proposes to prohibit the board from taking enforcement action against the self referred licensee based on their entry into the program or any information obtained from the licensee while participating in the program. This change more closely mirrors the diversion programs operated by other boards in the department. The proposal does allow the board to take an enforcement action against a licensee in the program if the board independently obtains information supporting such an action.

Another substantial change is to section 4368, which removes the mandate that the board enter into a contract with a professional association to promote the program and coordinate outreach to encourage voluntary participation. The board has not entered into such a contract with a professional association for over five years. Given the current fiscal constraints on the board, it is unlikely that such a contract would be reestablished in the foreseeable future and removing the statutory mandate would seem appropriate. The board can use other means to educate licensees about the availability of the program. The board could always enter into such a contract, if it desired, without the statutory mandate.

It was asked if the board had considered including pharmacy technicians in the program. It was noted that the intent is to rehabilitate pharmacists so that they may return safely to the practice of pharmacy. As a health professional, the pharmacist has much more invested in their education and training and thus more incentive to seek treatment. The program also encourages the pharmacist's participation and rehabilitation while providing the oversight necessary to ensure patient safety without undue punishment to the impaired pharmacist.

The Enforcement Committee recommended that the Board of Pharmacy support the proposed legislative changes relating to the Pharmacists Recovery Program.

Proposed Legislative Change to Update the Law Regarding the Pharmacy Technician Program (Bus. & Prof. Code section 4115 and 4115.5)

The Enforcement Committee was provided with proposed changes to the pharmacy technician program. It was emphasized that most of the changes are technical and designed to make the statutes more clear. The most significant change is standardizing the terminology relating to the supervision of ancillary personnel. The different code sections used slight variations of language requiring the supervision of ancillary personnel. This draft adopts the most common verbiage of "direct supervision and control" of the pharmacist and applies this same supervision to interns. Concern was expressed that the supervision was limited to the dispensing of prescriptions especially as it pertains to interns. The committee agreed with this concern and directed that the language be modified accordingly.

The other changes are mostly technical clean up to eliminate duplicative and unnecessary language. However, one substantive change to 4115 is made to eliminate the exemption that

permits unlicensed personnel to act as a pharmacy technician during their first year of employment at the Department of Corrections, California Youth Authority, Department of Mental Health, Department of Developmental Services or the Department of Veterans Affairs. This provision was added to allow personnel to work in those facilities until they could accumulate enough hours to qualify for licensure as a pharmacy technician. However, experience is no longer a means of qualifying for licensure as a pharmacy technician and this provision is no longer appropriate.

Comments were made that provided general support with the proposed changes with an opportunity for the board to consider some possible enhancements. It was reiterated that the intent of this legislative proposal was not to change the ratio or the basic authority of pharmacy technicians. As legislation is introduced, the opportunity to address these issues is always available.

The Enforcement Committee recommended that the Board of Pharmacy support the proposed legislative changes to the pharmacy technician program.

Proposed Legislative Change to Related to Letter of Admonishment (Bus. & Prof. Code section 4315)

The Enforcement Committee considered a revision to Section 4315, which authorizes the executive officer of the board to issue a letter of admonishment for a violation of the Pharmacy Law. This section was added last year to provide the board with a broader range of enforcement options. One requirement in the new section is that the licensee receiving the Letter of Admonishment must keep a copy of that letter in the pharmacy for three years. This requirement is problematic for licensees that do not work regularly in the same pharmacy or do not work in a pharmacy at all (exemptee, wholesaler, etc.). Accordingly, it is recommended that this requirement be eliminated.

The Enforcement Committee recommended that the Board of Pharmacy support the proposed change to section 4315.

Proposed Regulation Change to Implement SB 1913 Related to the Use of Technologies to Record the Identification of a Pharmacist

Senate Bill 1913 amends Section 4115 to permit the board to allow the use of electronic technologies to satisfy the requirement that a pharmacist sign off on prescriptions filled by pharmacy technicians. The proposed regulation text would allow the use of electronic methods of identifying the reviewing pharmacist. This section would also be an alternative means of documenting the pharmacist's review as required by CCR, title 16, sec. 1717(b)(1) and 1717(g).

The Enforcement Committee recommended that the Board of Pharmacy support this proposed regulation change that would authorize the use of technologies to record the identification of the pharmacist in lieu of the pharmacist initialing or signing a prescription record or label.

Request by Longs Drug Stores for Waiver of 1717(e) to Install a 24-Hour Kiosk

Longs presented its request to install convenient, secure and private, 24-hour prescription drop kiosks. It was explained that the kiosk would be installed adjacent to or in the parking lot at various Longs Drug Stores in California, for patients to use as an easy means to drop off their prescriptions for the pharmacy to fill. The kiosk would be similar to a mailbox or drop off container used by video stores.

The Enforcement Committee advanced to the Board of Pharmacy the request from Longs Drug Stores for waiver of 1717(e) to use a 24-hour prescription drop kiosk; however, the committee did not make a recommendation regarding the request. Prior to the presentation by Longs Drug Stores, board member David Fong recused himself from the discussion.

Request by Longs Drug Stores for Wavier of 1717(e) to Install and Utilize Self-Service Dispensing Units

Longs Drug Stores requested a waiver of 1717(e) to install and utilize a self-service dispensing unit, such as the Asters ScriptCenter, at various Long Drug Stores in California.

Representatives of the Asters ScriptCenter provided an overview of the dispensing unit. It is an automated, self-contained instrument that allows patients to access their filled prescriptions. The units will be installed in close proximity to the pharmacy area. To improve patient convenience and therapeutic compliance, a patient may access the units during pharmacy hours or during those times when the main store is open, but the pharmacy is closed.

At the request of the patient and through the use of a secure method designed to guard against inappropriate access, a patient may retrieve his/her filled prescription from the unit at their convenience. New prescriptions, or those prescriptions requiring consultation, would not be available through these units.

Prescriptions would be filled by a pharmacist and placed into the units either by a pharmacist or pharmacy personnel, under the supervision of a pharmacist. As medications are placed into the units, security measures are used to ensure accurate dispensing.

The Enforcement Committee advanced to the Board of Pharmacy the request from Longs Drug Stores for waiver of 1717(e) to use a self-service dispensing unit; however, the committee did not make a recommendation regarding the request. Prior to the discussing the request from Longs Drug Stores, board member David Fong recused himself.

Proposed Regulation Change to Add Section 1713 – Delivery of Prescriptions

Based on the request from Longs Drug Stores to permit the use of secure drop boxes for receiving prescription orders from patients and to use secure devices for dispensing filled prescriptions, staff drafted a regulation change that would permit both these activities should the board grant the waivers.

The prescription drop boxes would allow patients to drop off prescriptions in a secure container that is at the same address of the pharmacy or adjoining the licensed premises. The secure devices for dispensing refill prescriptions after hours is restricted to refill prescriptions that are not subject to the consultation requirement. The proposed draft relocates existing provision 1717(e) into a new section and provides the authorization for both the drop boxes and self-service dispensing devices.

Concern was expressed that the Board of Pharmacy should not act on this proposed regulation or the waiver request to use the self-service dispensing device until the board has a philosophical discussion regarding pharmacist consultation on refill prescriptions. Currently, the law doesn't require pharmacist consultation on refill prescriptions (only in the pharmacist's professional judgment or upon a patient's request); however, use of these self-service dispensing devices would remove the pharmacist completely away from the process. It was noted that pharmacy law doesn't require the pharmacist to physically provide the patient with the refill medication; a cashier does this.

The Enforcement Committee moved this proposed regulation to the Board of Pharmacy for its consideration. The committee did not provide a recommendation.

Implementation of SB 151 – Changes to the Prescribing and Dispensing of Controlled Substances

The Enforcement Committee was provided more question and answers on changes to the law regarding the prescribing and dispensing of controlled substances especially as it to the new prescription forms and requirements. These questions have been added to the board's Web site.

It was reported that board is continuing its outreach efforts to educate all health professionals on these new changes.

Status Report on the Legislation Related to Wholesalers (AB 2682 and SB 1307)

It was reported that these bills strengthen the licensure and regulation of wholesalers by enacting comprehensive changes in the wholesale distribution system for prescription drugs and are awaiting the Governor's signature. The board carefully developed the provisions in these bills to directly address issues found during its investigations of wholesale violations in California and the recommendation for the changes came from this committee.

Discussion on How the Board of Pharmacy Can Improve Communication and Facilitate Communications with the Public and Licensees

At the board's July meeting, President Goldenberg stated that one of the priorities for his term is to improve the communication of the board with its licensees and with the public. To this end, each of the board's committees will hold a public meeting before the October board meeting

with this topic listed as a discussed item. The goal is to establish a dialogue with the stakeholders on improving communication, and to bring any suggestions to the next board meeting. The committee was provided with a copy of the memorandum that was prepared by the Assistant Executive Officer for the Communication and Public Education Committee. This document provided an overview of the several broad based means of communication that the board has with the public and its licensees.

A comment was made that the board has done an outstanding job at its many outreach efforts especially the programs on pharmacy law and much of the feedback has been. It was noted however that the best communication that the board can offer is the dialog that board inspectors have with licensees and informing them of the tools that are available. However, concern was expressed that there is a disconnect between the inspector and the board. It was encouraged that the inspection focuses on education first. As previously suggested at other meetings, the board was encouraged to hold its meetings at the schools of pharmacy.

Review of Draft Self-Assessment Forms

Chair William Powers noted that the draft self-assessment forms were not completed for review at this meeting. However, section 1715 requires that the pharmacist-in-charge complete a self-assessment by July 1, of every odd year. It is the intent of the board to update the self-assessment forms with the many new law changes so that it can be used by July 1, 2005. To do this, the board must review the forms at its October meeting so that it can act on the regulation change at the January board meeting.

Discussion Regarding Routine Compliance Inspections and Citation and Fine Program

Inspections
Supervising Inspector Dennis reported that in July 2001, the board reinstated its routine inspection program with the goal of inspecting every pharmacy within 3 years. The compliance team will meet this goal by June 30, 2005. Although the team has done a tremendous effort within existing resources to meet the three-year goal, the projections did not take into consideration the licensure of approximately 600 new pharmacies a year or the implementation of the sterile compounding program for which the board did not receive new inspector positions. The compliance team plans to inspect over 1,500 pharmacies by the end of this fiscal year.

The Enforcement Committee acknowledged and commended the inspectors for their efforts.

Citation and Fine Program
It was reported to the Enforcement Committee for the period of May 1, 2001 – September 21, 2004, the board has issued 1,843 citation and fines. Of these, 135 citations with fines totaling over $300,000 have not been collected. This is approximately 7% of the total number of citations issued and 20% of the fines. A large number of these citations are issued to cancelled/unlicensed pharmacy technicians, unlicensed premises and cancelled premises. Often times, the citations and fines are issued so that a public record is made, understanding that is

more than likely that the fine may not be collected. Staff advised the committee that it is exploring options on the collection of these unpaid fines.

New DEA Controlled Substances Registration Forms

The Enforcement Committee was given a letter from the DEA advising that as of October 1, it will change the style and appearance of the registration certificate. It will consist of two parts: one that can be displayed on the wall and a smaller wallet size version. The certificate will have an embedded watermark logo, to provide authentication and to deter counterfeiting. The DEA asked that this information be shared with licensees and will appear in the board's next newsletter.

Adjournment

Committee Chair William Powers adjourned the meeting at 12:30 p.m.

ATTACHMENT P

California State Board of Pharmacy
400 R Street, Suite 4070, Sacramento, CA 95814-6237
Phone (916) 445-5014
Fax (916) 327-6308

STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
Arnold Schwarzenegger, Governor

Enforcement Team Meeting
September 29, 2004

1:45 p.m. – 3:00 p.m.

Present: Committee Chair and Board Member William Powers
President and Member Stan Goldenberg
Executive Staff
Supervising Inspectors
Inspectors

Announcements/Introductions
Committee Chair William Powers called the meeting to order at 1:45 p.m.

Quality Improvement Efforts
Supervising Inspector Robert Ratcliff provided the quarterly management reports. A pharmacy owner and a pharmacist-in-charge discussed with the inspectors their perception of a recent inspection and offered suggestions for improving the process.

Discussion of Enforcement Committee Meeting
The Enforcement Team discussed the agenda items from the Enforcement Committee meeting.

Adjournment
Committee Chair William Powers adjourned the meeting at 3:00 p.m.

ATTACHMENT Q

Board of Pharmacy Enforcement Statistics
Fiscal Year 2004/2005

Workload Statistics	July-Sept	Oct-Dec	Jan-Mar	Apr-June	Total 04/05
Complaints/Investigations					
Initiated	366				366
Closed	584				584
Pending (at the end of quarter)	629				
Cases Assigned & Pending (by Team)					
Compliance Team	59				59
Drug Diversion/Fraud	57				57
Mediation Team	189				189
Probation/PRP	45				45
Enforcement	4				4
Application Investigations					
Initiated	41				41
Closed					
Approved	13				13
Denied	2				2
Total*	27				27
Pending (at the end of quarter)	54				
Citation & Fine					
Issued	197				197
Abated	336				336
Total Fines Collected	$113,136.00				$113,136.00

* This figure includes withdrawn applications.

** Fines collected and reports in previous fiscal year.

Board of Pharmacy Enforcement Statistics
Fiscal Year 2004/2005

Workload Statistics	July-Sept	Oct-Dec	Jan-Mar	Apr-June	Total 04/05
Administrative Cases (by effective date of decision)					
Referred to AG's Office*	31				31
Pleadings Filed	22				22
Pending					
Pre-accusation	68				
Post Accusation	79				
Total	155				
Closed**	19				19
Revocation					
Pharmacist	2				2
Pharmacy					
Other	2				2
Revocation,stayed; suspension/probation					
Pharmacist	1				1
Pharmacy					
Other					
Revocation,stayed; probation					
Pharmacist	5				5
Pharmacy					
Other					
Suspension, stayed; probation					
Pharmacist	1				1
Pharmacy					
Other					
Surrender/Voluntary Surrender					
Pharmacist	1				1
Pharmacy					
Other	4				4
Public Reproval/Reprimand					
Pharmacist	1				1
Pharmacy					
Other					
Cost Recovery Requested	$49,126.50				$49,126.50
Cost Recovery Collected	$45,201.47				$45,201.47

* This figure includes Citation Appeals

** This figure includes cases withdrawn

Board of Pharmacy Enforcement Statistics
Fiscal Year 2004/2005

Workload Statistics	July-Sept	Oct-Dec	Jan-Mar	Apr-June	Total 04/05
Probation Statistics					
Licenses on Probation					
Pharmacist	105				105
Pharmacy	20				20
Other	23				23
Probation Office Conferences	7				7
Probation Site Inspections	23				23
Probationers Referred to AG for non-compliance	0				0

As part of probation monitoring, the board requires licensees to appear before the lead inspector at probation office conferences. These conferences are used as 1) an orientation to probation and the specific requirements of probation at the onset, 2) to address areas of non-compliance when other efforts such as letters have failed, and 3) when a licensee is scheduled to end probation.

Pharmacists Recovery Program (as of 9/30/04)

Program Statistics					
In lieu of discipline	0				0
In addition to probation	3				3
Closed, successful	0				0
Closed, non-compliant	3				3
Closed, other	1				1
Total Board mandated Participants	42				42
Total Self-Referred Participants*	30				30
PRP Site Inspections**	11				
Treatment Contracts Reviewed	38				38

Monthly the board meets with the clinical case manager to review treatment contracts for scheduled board mandated participants. During these monthly meetings, treatment contracts and participant compliance is reviewed by the PRP case manager, enforcement coordinator and lead inspector and appropriate changes are made at that time and approved by the executive officer. Additionally, non-compliance is also addressed on a needed basis e.g., all positive urines screens are reported to the board immediately and appropriate action is taken.

* By law, no other data is reported to the board other than the fact that the pharmacists and interns are enrolled in the program.

**Some PRP Participant Inspections are included in the Probation Site Inspections total.

As of September 30, 2004.

ATTACHMENT R

Board of Pharmacy
First Quarterly Report
July - October 2004

Enforcement Committee

Goal 1:	**Exercise oversight on all pharmacy activities.**
Outcome:	**Improve consumer protection.**

Objective 1.1:	**To achieve 100 percent closure or referral on all cases within 6 months by June 30, 2005:**
Measure:	**Percentage of cases closed or referred within 6 months**
Tasks:	*(Based on 228 mediations/investigations sent to SI for review)* 1. Mediate all consumer complaints within 90 days. **0-90 Days 34 (68%)** **91-180 Days 13 (26%)** **181-365 Days 2 (4%)** **366-730 Days 1 (2%)** 2. Investigate all other cases within 120 days. **0-90 Days 64 (36%)** **91-180 Days 73 (41%)** **181-365 Days 32 (18%)** **366-730 Days 9 (5%)** *(Based on 575 closed investigations/mediations)* 3. Close (e.g. issue citation and fine, refer to the AG's Office) all board investigations and mediations within 180 days. **0-90 Days 177 (31%)** **91-180 Days 182 (32%)** **181-365 Days 148 (26%)** **366-730 Days 61 (11%)** **731+ 1 7 (1%)** 4. Seek legislation to grant authority to the executive officer to issue a 30-day Cease and Decease Order to any board-licensed facility when the operations of the facility poses an immediate threat to the public.

Objective 1.1, cont'd **Tasks**	5. Integrate data obtained from computerized reports into drug diversion prevention programs and investigations (CURES, 1782 reports, DEA 106 loss reports). **CURES** ♦ *The Board has requested the addition of several critical date fields to the CURES system to ensure meaningful and accurate reports: 1) the date CURES was last updated by DOJ; 2) the date data was received at AAI from the pharmacy; and 3) the date data was transmitted from AAI to BNE. The date CURES was last updated is now available. Do to limitations in the current programming and since we are currently in the process of moving to a web based system, BNE has placed the other two date requests on hold until early 2005. No changes this quarter.* **23 CURES reports were provided to supervising inspectors and/or inspectors this quarter to aid in an investigation or inspection.** **CURES data were used in 26 complaint investigations.** **CURES compliance issues were found in 14 inspections.** ♦ *1782 Wholesaler Database - no change this quarter.* ♦ *DEA 106 Theft/Loss Report- no changes this quarter.* 6. Re-establish the CURES workgroup that includes other regulatory and law enforcement agencies to identify potential controlled substance violations and coordinate investigations. ♦ *The CURES Users Group continues to meet the third Tuesday of every month. Meetings were held on July 20 and September 21st (the August meeting was canceled) to work on pharmacy noncompliance and data issues as well an improving database functionality.* ♦ *Board met with BNE to discuss the board's needs for standard reports to be included on the new web-based CURES database scheduled for implementation by the end of this year. The board provided BNE with various samples of board-developed reports currently in use. In addition, staff highlighted numerous issues with BNE-developed standard reports available on the current system. Staff is currently working on updating business requirements and completing formal report development specifications documents.*

Objective 1.1, cont'd **Tasks**	***CURES Users Group Meetings: Meetings are schedule for October 26 and November 30th. No meeting is scheduled for December due to the holidays.*** ♦ *Inspector and supervising inspector continue to participate on the monthly diversion task force meetings regarding the importation of dangerous drugs, repackaging and distribution in the U.S.; monthly Oxycontin task force meetings in Ventura; FBI task force meetings; and diversion task force meetings in San Diego.* 7. Secure sufficient staffing for a complaint mediation team and to support an 800 number for the public. 8. Improve public service of the Consumer Inquiry and Complaint Unit. ▪ *Board complaint staff provided information and brochures at the Asian Community Fair on July 15 in Sacramento and at the San Diego Better Business Bureau's Consumer Expo on August 7, 2004.* ▪ *Board staff provided consumer information at an adult day care program in Carmichael on September 28.* ▪ *In September the board staffed a booth at the Yreka Health Fair where about 450 people attended the event.* ▪ *The board staffed a booth at the Sixth Annual Los Angeles County Health Fair and Senior Exposition on October 7. Nearly 1,000 people attended* ▪ *Board has 21 consumer brochures available, including Health Notes.* ▪ *Board staff provided information about the board and discount programs for drugs at the Triple "R" Adult Day Program in Sacramento on September 28.* ▪ 9. Automate processes to ensure better operations and integrate technology into the board's investigative and inspection activities. ▪ *A request to provide the board the capability to download its entire CAS enforcement database into an Access database has been submitted to the department's Office of Information Systems. This modification will enhance the board's reporting*

	capabilities. If approved by OIS, January 1, 2005 is the target date for implementation. ♦ *Revisions made to the automated inspection system this quarter include:* ▪ *Modified import specification of Teale data into Access.* ▪ *Improved reports in assignment program.* ▪ *Improved functionality of Inspector Data program. Now prints nonlicensed staff titles and totals the number of staff employed and present. Inspection report prints license as well as LSC 12345/PHY 67890 when inspecting a LSC site. Improvements to be installed by the end of October.* ▪ *Added LSC license category to Inspector Activity to more accurately track inspector time.* o Developed and implemented a behind-the-scenes weekly email delivery of an assigned versus completed inspection report to the supervising inspector. This is a weekly status report that shows inspections assignments completed and inspections assignments yet to be completed for each inspector. No changes this quarter. ▪ Automated evidence database – No changes this quarter. ▪ Automated sterile compounding database - No changes this quarter ▪ Audit Program - Developed new and improved reports. Audit program is used to capture data from over 41,000 prescriptions. ♦ *Security Printer database revisions and improvements this quarter include: various functionality revisions to ease data entry, a new status report and statistical summary that is set to automatically e-mail an updated version to management weekly, a worksheet style report that can be printed and included inside the file cover for easy reference.*
Objective 1.2: **Measure:**	**To achieve 100 percent closure on all administrative cases within one year by June 30, 2005.** **Percentage closure on administrative cases within 1 year**

Tasks: **Objective 1.2 cont'd.**	1. Pursue permanent funding to increase Attorney General expenditures for the prosecution of board administrative cases. ▪ *April 1st DAG costs increased from $112-$120 per hour to $132 per hour and Legal Assistants hourly costs increased from $53 to $91. Before this increase in fees, the board projected a deficit of $35,000. For 2003/04 the board will have to absorb the increased costs. For 2004/05 the board redirected $70,000 to the AG budget line item rather than pursuing an augment by a BCP.* ▪ *July 1 DAG costs increase to $139 per hour. Board receives supplemental funding of $216 thousand to purchase the same level of AG services at a higher hourly rate.* 2. Aggressively manage cases, draft accusations and stipulations and monitor AG billings and case costs. ▪ *Case management and review of pending cases is a continuous process.* ***Status memos sent this quarter: 26.*** ▪ *Disciplinary cases closed this quarter:* **0-365 days 8 (38.10%)** **366+ days 13 (61.9%)** ▪ Disciplinary cases reviewed this quarter: ***Accusations reviewed: 27*** ***Accusations needing revision: 10*** ***Accusations filed: 22*** ***Stipulations/proposed decisions reviewed: 18*** ***Cases reviewed for costs: 12*** 3. Establish a disciplinary cause of action for fraud convictions similar to current cash compromise provisions related to controlled substances. 4. Automate processes to ensure better operations and integrate technology into the board's investigative and inspection activities. ▪ *Administrative Case Management Database Program -* ✓ Changed calculations to reflect change in Legal Analyst and Deputy Attorney General Costs (changes effective April 2004 and July 2004). ✓ Added a report to view cases that had status checks completed during a certain time frame. ✓ Added a report to view Administrative Law Judge costs per case.

	✓ Linked the database with the Activity Tracker database. Added reports and more fields to the cost form for easier access and viewing of inspector costs for each case. 5. Review and update disciplinary guidelines. ▪ *No changes from last quarter.*

Objective 1.3: **Measure:**	**Inspect 100 percent of all licensed facilities once every 3 years by June 30, 2004.** **Percentage of licensed facilities inspected once every 3 years**
Tasks:	1. Automate processes to ensure better operations and integrate technology into the board's investigative and inspection activities. ▪ *See response to Objective 1.1, Task #9.* 2. Inspect licensed premises to educate licensees proactively about legal requirements and practice standards to prevent serious violations that could harm the public. *For this quarter:* *Total number of locations identified to inspect at the time of the inspection program's inception (does not include sites licensed after 07/01/2001) to meet the board's goal of inspecting all sites every 3 to 4 years was approximately **5,933;** total number of inspections completed **5,302**, total number of inspections to be completed by July 2005 are **631.*** *Total number of locations identified to inspect (including sites licensed after 07/01/2001) was approximately **8,155;** total number of inspections completed **6,849;** total number of inspections to be completed by July 2005 are **1,036.*** *Total number of inspections completed this quarter:* ***657*** *(This is all inspections combined i.e., routine, diversion, probation/PRP, sterile compounding, status 3 (delinquent), CURES, inspections as a result of a complaint investigation, etc)* *Of those inspections, there were:*

	Total Sterile Compounding Inspections: ***44*** *Total Status 3 (delinquent) inspections:* ***3*** *Total routine inspections resulting in a complaint investigation:* ***9*** 3. Seek legislation to mandate that periodic inspections be done on all board-licensed facilities.
Objective 1.4: **Measure:**	**Develop 4 communication venues in addition to the inspection program to educate board licensees by June 30, 2005.** **Number of communication venues (excluding inspection program)**
Tasks:	1. Develop the board's website as the primary board-to-licensee source of information. ▪ *Public disclosure of disciplinary history on licensees is online.* ▪ *During this quarter website revisions included:* ✓ ***Regulations updates.*** ✓ ***Added the option to join the Boards e-mail notification list.*** ✓ ***Posted Memo to Pharmacists on dispensing CII drugs without security or triplicate forms.*** ✓ ***Posted an audio recording of a presentation on SB 151*** ✓ ***Listed frequently asked questions on SB 151.*** ✓ ***Posted Board and Committee Meeting information - agenda, materials and minutes.*** ✓ ***Revised 2004 Pharmacy Lawbook*** ✓ ***Revised Key Facts about Emergency Contraception.*** ✓ ***Added Regrade Procedures for Pharmacist Examination.*** ✓ ***Added additional Security Printers and their distributors (total 25)*** 2. Prepare two annual *The Scripts* to advise licensee of pharmacy law and interpretations. ▪ *March 2004 Script published* ▪ *November 2004 Script in production*

Objective 1.4, cont'd.	3. Update pharmacy self-assessment annually. ▪ *October 2004 - Revisions complete, being reviewed at October board meeting..* 4. Develop board-sponsored continuing education programs for pharmacists in the area of pharmacy law and the expectations of the pharmacist-in-charge and coordinate presentations at local and annual professional association meetings throughout California. ▪ *C/E presentations given this quarter:* ➢ Board staff presented information to approximately 25 pharmacists regarding new controlled substances requirements at a leadership meeting of the Sacramento Valley Health System Society of Pharmacists (June 28). ➢ Board staff presented information to law enforcement agencies about CURES and drug diversion (May 27 and 28, not previously reported). ➢ Board staff presented information to audit staff of the Department of Health Services (June 30, not reported previously). ➢ Board staff presented information about compliance with California's sterile compounding requirements and radiopharmacy on July 8 to a group of about 10 pharmacists to a group in Southern California. ➢ Board staff presented information about the new prescribing requirements for controlled substances to physicians in San Luis Obispo on July 14, and to pharmacists and law enforcement staff on July 15. ➢ Board staff presented information about prescribing and dispensing controlled substances under the new California requirements to a group of over 40 physicians and other health care providers on August 3. ➢ Board staff presented information about drug diversion investigations to investigators of the Department of Justice on August 26.

Objective 1.4 (cont'd)	➢ Board staff presented information regarding the new requirements for controlled drugs to investigators and staff pharmacists of the Department of Health Services on September 8, and to more than 50 pharmacists, physicians and other health care providers at a presentation hosted by the Pharmacy Foundation of California and Catholic Healthcare West. ➢ Board staff provided a major presentation at the CMA's annual pain conference in Sacramento on September 10 to more than 600 providers. ➢ President Goldenberg and Supervising Inspector Nurse presented information about new controlled substances requirements to the San Diego ASCP Chapter on September 13. ➢ Staff presented information about quality assurance programs and sterile compounding to the Sacramento Valley Society of Health Systems Pharmacists on September 17. ➢ Staff presented information about the board and new controlled substances requirements to the UCSF Medical Center on September 21. ➢ Board staff presented information about drug diversion investigations to investigators of the Department of Justice on September 28. ➢ Staff presented information about the new controlled substances requirements to a group of approximately 100 pharmacists, physicians and other health care providers at St Mary's Medical Center in Orange County on September 30. ➢ Board staff represented the board at the Circle of Advisors Meeting (regarding emergency contraception) on October 5. ➢ Supervising Inspector Ratcliff was a speaker at the California Primary Care Association's Tenth Anniversary ➢ Conference 0n October 7th ➢ Board Member Jones represented the board as a speaker at the Indian

	Pharmacist Association on October 9, ➢ where approximately 500 individuals attended. ➢ In October board presented a telephone session on the new controlled substances requirements with health care providers in Redding. ➢ Board staff presented information about new controlled substances requirements to Santa Clara Medical Society. ➢ Supervising Nurse provided information about the new controlled substances requirements to the general public at a HICAP meeting in October.

Objective 1.6: **Measure:**	**Respond to 95 percent of all public information requests within 10 days by June 30, 2005.** **Percentage response to public information requests within 10 days**
Tasks: Objective 1.6, cont'd.	1. Activate public inquiry screens to expand public information. Establish web look-up for disciplinary and administrative (citation) actions. ▪ *Teale Public Disclosure Screen – Completed disciplinary actions are entered into the database on a going-basis.* ▪ *Web Enforcement Look-Up – In production.* ▪ Establish on-line address of record information on all board licensees. ▪ *Licensee address of record information became available on-line to the public in December.* 3. Respond to specialized information requests from other agencies about board programs, licensees (e.g. subpoenas) and Public Record Act requests. ▪ *In the last quarter the board responded to:* ***31 public records requests-77% within 10 days; 23% over 10 days.*** ***35 requests from licensees – 77% within 10 days; 23% over 10 days.*** ***16 requests from other agencies – 81% within 10-day response time; 19% over 10 days.***

	227 written license verifications – 64% within 10 days; 36% over 10 days. ***5 subpoenas – 100% responded to within 5 days.***
Objective 1.7 **Measure:**	**Initiate policy review of 25 emerging enforcement issues by June 30, 2005.** **The number of issues**
Tasks (Issues):	1. Reimportation of drugs from Canada. ▪ Importation of Drugs 2. Modification to the Quality Assurance Regulation regarding patient notification. 3. Proposals regarding wholesale transactions. ▪ Sponsored legislation (SB 1307). 4. Clarification regarding prescription records by authorized officers of the law. 5. Review of Pharmacy Law regarding the delivery of medications after the pharmacy is closed and a pharmacist is not present. ▪ Sponsored legislation SB 1913 6. Off-site order entry of hospital medication orders (Bus. & Prof. Code Section 4071.1). 7. Prescriber dispensing. 8. Implementation of federal HIPAA requirements. 9. Prohibition of pharmacy-related signage. 10. Implementation of enforcement provisions from SB 361. 11. Implementation of SB 151 (elimination of the Triplicate). 12. Dispensing non-dangerous drugs/devices pursuant to a prescriber's order for Medi-Cal reimbursement
	13. Authorized activities in a pharmacy. 14. Review of Quality Assurance Program. 15. Limited distribution and shortage of medications. 16. Conversion of paper invoices to electronic billing. 17. Automated dispensing by pharmacies. 18. Public disclosure and record retention of substantiated complaints. 19. Evaluation of QA regulation 20. Biometric technology ▪ Statutory change (SB 1913), regulation proposal to implement. 21. Update of pharmacy laws related to PRP. 22. Update of pharmacy law related to pharmacy technicians. 23. Clean-up of "Letter of Admonishment" provision. 24. Use of "kiosks: for drop-off of prescriptions. 25. Use of self-services dispensing units for pick-up of refill prescriptions.